Supreme Court, U.S.
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No. 03-

IN THE

Supreme Court of the United States

ALLERGAN, INC., AND ALLERGAN SALES, INC.,
Petitioners,

v.

ALCON LABORATORIES, INC., ALCON RESEARCH, LTD., ALCON UNIVERSAL, LTD., AND BAUSCH & LOMB INCORPORATED,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

The Drug Price Competition and Patent Term Restoration Act of 1984 authorizes generic drug manufacturers to seek approval from the Food and Drug Administration to market generic versions of previously approved drugs through Abbreviated New Drug Applications, or ANDAs. That Act also amended the Patent Act by adding § 271(e)(2), which provides that:

> It shall be an act of infringement to submit—
>
> . . . an [ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

The question presented is:

Whether § 271(e)(2) permits a patentee to bring an infringement action upon the filing of an ANDA "for a drug . . . the use of which is claimed in a patent," as the plain language of the statute states, or whether such an action can only be brought only upon the filing of an ANDA "for a drug . . . the use of which is claimed in a patent *and is listed in the ANDA*," as the Federal Circuit ruled below.

PARTIES TO THE PROCEEDINGS

All parties to the proceedings are listed in the caption to this petition. Allergan Sales, Inc. is now Allergan Sales, LLC. Allergan, Inc. is the sole shareholder of Allergan Sales, LLC. Allergan, Inc. does not have any parent corporation and no publicly traded company owns 10% or more of its stock.

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OPINIONS BELOW

The opinion of the Federal Circuit (App. 1a-44a) was entered on March 28, 2003, and is reported at 324 F.3d 1322 (Fed. Cir. 2003). The order denying the Petition for Rehearing (App. 69a-70a) was entered on May 22, 2003 and is unreported. The decision of the district court (App. 45a-68a) was entered on May 8, 2002, and is reported at 200 F. Supp. 2d 1219 (C.D. Cal. 2002).

JURISDICTION

The Federal Circuit entered its judgment in this case on March 28, 2003, and denied the Petition for Rehearing en Banc on May 22, 2003. On August 13, 2003, the Chief Justice extended the time for filing a petition for writ of certiorari until September 19, 2003. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

Section 271(e)(2) of the Patent Act, 35 U.S.C. § 271(e)(2), provides, in relevant part, that:

> It shall be an act of infringement to submit—
>
> (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

STATEMENT OF THE CASE

This case raises the important issue of what rights patentees have under the patent litigation provision of the Drug Price Competition and Patent Term Restoration Act of 1984 (the

"Hatch-Waxman Act"), 35 U.S.C. § 271(e)(2), to enforce patents that claim novel methods of using drugs to protect health or to treat illness. In the decision below, the Federal Circuit ruled that the Act affords no protection to method of use patents that claim so-called "off-label" uses—*i.e.*, uses for which the Food and Drug Administration ("FDA") has not approved the drug, but for which physicians can and often do prescribe it—or that protect only one of several FDA approved uses. As a result, the decision below effectively destroys incentives for manufacturers to make the substantial investments necessary to discover and develop new therapeutic and potentially life-saving uses of existing drugs.

The decision in this case is particularly remarkable because all three members of the panel below openly disagreed with the judgment they rendered. Bound by another panel decision issued just months earlier, the panel below upheld dismissal of a patent action that all three judges agreed was authorized by the plain language of § 271(e)(2). In an extraordinary move, each member of panel below wrote or joined a concurring opinion to explain why the earlier and controlling opinion in *Warner-Lambert Co.* v. *Apotex Corp*, 316 F.3d 1348 (Fed. Cir. 2003) is wrong, and why none of the policy arguments *Warner-Lambert* panel relied upon provided a basis for ignoring the statute's plain language.

Despite this sharp division between two panels, the Federal Circuit declined to rehear this case en banc. That refusal leaves in place a controlling interpretation of federal law that, as the panel below cogently explained, is manifestly incorrect. That erroneous interpretation, moreover, was driven by a misguided view of so-called "off-label" use of FDA-approved drugs—a view that failed to recognize that a generic drug manufacturer can, consistent with federal law, seek FDA approval for one use of a drug with knowledge and intent that the drug will be prescribed for "off-label" uses that infringe a valid method of use patent. The Federal Circuit's mis-interpretation of § 271(e)(2) adversely affects the public

health and safety by depriving pioneer drug manufacturers of the financial incentives to research and develop innovative new uses for existing medications. The proper interpretation of § 271(e)(2) is thus an issue of exceptional importance worth of this Court's review.

A. Statutory Background

In the Hatch Waxman Act, Congress sought to strike a careful balance between two competing interests—protecting the patent rights of pioneer drug manufacturers and fostering legitimate generic drug competition. Both of these interests had been adversely affected by 1962 amendments to the Food, Drug, and Cosmetic Act ("FDCA") that required all manufacturers to demonstrate through well-controlled studies that their products are safe and effective for their intended use. 21 U.S.C. § 355(d). By preventing manufacturers from exploiting their patented inventions until the lengthy testing and FDA review process was completed, these requirements deprived pioneer drug manufacturers of years of patent protection on their patents. See *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 669-71 (1990). At the same time, the costs of the testing and review process were so great that generic versions of numerous name brand drugs remained unavailable years after the patents on those drugs expired. H.R. Rep. No. 98-857, pt. 1, at 17 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2650. In addition, generic competition was further hampered by the Federal Circuit's 1984 ruling that the manufacture, sale and use of a patented drug constituted an act of infringement even when done solely to perform testing to collect data needed to apply for regulatory approval. See *Roche Prods., Inc.* v. *Bolar Pharm. Co.*, 733 F.2d 858, 862-63 (Fed. Cir. 1984).

The Hatch-Waxman Act responded to these problems in a number of ways. In order to restore the years of patent protection lost as a result of the testing and approval process, the Act authorizes the Patent & Trademark Office to extend the terms of patents on pioneer drugs and methods of using

drugs. 35 U.S.C. § 156. The Act also grants periods of exclusive FDA regulatory approval to manufacturers who invest in the costly safety and efficacy testing necessary to obtain approval of a New Drug Application ("NDA"). 21 U.S.C. § 355(c)(3)(D)(ii).

On the other hand, the Act facilitates generic competition by authorizing the filing of Abbreviated New Drug Applications ("ANDAs") for generic copies of pioneer drugs. The Act permits a generic manufacturer to rely on testing performed by the pioneer, provided the generic product is bioequivalent to the approved pioneer product. *Id.* § 355(j)(2)(A)(iv). The Act also overruled the Federal Circuit's decision in *Bolar* by adding § 271(e)(1) to the Patent Act, which provides that it is not an act of infringement to make, use, offer to sell, or sell a patented invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." 35 U.S.C. § 271(e)(1).

At the same time that Congress eliminated the economic and legal barriers to legitimate generic drug competition, however, Congress also sought to ensure that such competition did not undermine the patent rights of pioneer drug manufacturers, and the crucial research incentives such patent rights create. Congress clearly recognized that the value of patents on drugs or methods of using drugs is severely undermined once generic versions of the drug enter the market. The system Congress designed to protect patent rights, therefore, seeks to resolve any claim that a generic infringes a patent on a drug or method of use *before* the FDA approves a generic.

Under this system, an NDA holder must give notice to ANDA applicants of its patent rights by listing with the FDA any unexpired patent on an approved drug or on any patent "which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the

manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1) & (c)(2). An ANDA applicant must, in turn, include, as part of its application for FDA approval, a certification:

> with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section–
>
> (I) that such patent information has not been filed,
>
> (II) that such patent has expired,
>
> (III) of the date on which such patent will expire, or
>
> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

Id. § 355(j)(2)(A)(vii).

If the ANDA applicant files a "paragraph IV" certification, it must give the owner of the patents notice of the ANDA and a statement explaining why it believes the patents are not infringed and/or are invalid. *Id.* § 355(j)(2)(B)(ii). The patentee then has 45 days to sue for infringement. *Id.* § 355(j)(5)(B)(iii). If the patentee sues within that time, the FDA will stay approval of the ANDA for 30 months, or until a court decides either that (1) the patent is infringed and not invalid, in which case the FDA will stay approval until the patent's date of expiration, or (2) the patent is not infringed or is invalid, in which case the FDA will automatically lift its stay. *Id.* If the parties' rights have not been adjudicated, the stay is also automatically lifted after 30 months. *Id.*

To ensure that federal courts can exercise jurisdiction over the infringement actions contemplated by this scheme, the Act also added § 271(e)(2) to the Patent Act. That provision states that:

> It shall be an act of infringement to submit—
>
> . . . an [ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2)(A).

B. "Off-Label" Use Of FDA-Approved Drugs

Central to the dispute in this case is the practice of so-called "off-label" use of FDA-approved drugs. The FDA approves an NDA only if "well-controlled clinical investigation[s]" demonstrate that the drug is safe and effective for its labeled use. 21 U.S.C. § 355(d). Because an ANDA relies on investigations conducted by an NDA holder, an ANDA applicant can only seek approval for a labeled use the FDA has previously approved. *Id.* § 355(j)(2)(A)(i).

Because the FDA does not regulate the practice of medicine, however, "the prescription of drugs for unapproved uses is commonplace in modern medical practice and ubiquitous in certain specialties." *Washington Legal Found.* v. *Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000). Indeed, "[o]ff-label use is not only legal and ethical, but is a common and integral feature of medical practice. The pace of medical discovery runs far ahead of FDA's regulatory machinery, and off-label use is frequently 'state-of-the-art treatment.'" James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71, 79 (1998). Prescriptions for off-label uses of drugs "may account for more than 25% of the approximately 1.6 billion prescriptions written each year, with some recent estimates running as high as 60%." *Id.* at 80 (internal quotation marks omitted). The FDA itself has recognized that "'unlabeled' uses may be appropriate and

rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature." *Use of Approved Drugs for Unlabeled Indications,* 12 *FDA Drug Bulletin: Information of Importance to Physicians and Other Health Care Professionals* (FDA, Rockville, Md.) Apr. 1982, at 4-5.

Thus, manufacturers can seek approval for one use of a drug with the knowledge and intent that, if approved, the drug will be prescribed for other uses. Moreover, manufacturers often make information about off-label uses of their products available to physicians, for example, by posting independent medical literature on their websites. It is against this regulatory and medical backdrop that petitioner's infringement action arose.

C. Petitioner's Method Of Use Patents

Petitioner holds two patents that claim a method of using brimonidine, a substance originally covered by a patent issued to Pfizer, Inc. In the late 1980s, petitioner began testing brimonidine as a treatment for open-angle glaucoma, an incurable disease that leads to blindness. For decades, medical professionals believed that this disease was caused when watery fluid in the eye fails to drain properly, thereby increasing intraocular pressure ("IOP"). Accordingly, the only known drug therapy for open-angle glaucoma was to lower IOP in an attempt to slow the disease's progression.

After years of expensive research and testing, petitioner demonstrated the drug's safety and efficacy in treating open-angle glaucoma and submitted an NDA for such use of brimonidine in 1995. The FDA approved the NDA the following year. It granted petitioner its five years of regulatory approval exclusivity, as well as the additional six-month exclusivity for conducting pediatric studies.

Beginning in the mid-1990s, researchers, including the named inventors of the patents-in-suit, began to understand that vision loss and blindness may result not only from

elevated IOP, but also from disease of the optic nerve itself. This realization started from the observation that a large percentage of patients with open-angle glaucoma have statistically normal IOP while showing progressive loss of vision, while many people with statistically elevated IOP never develop glaucoma at all. As a result of this research, open-angle glaucoma is now defined as a neurodegenerative disease, instead of a disease of elevated IOP.

At around this same time, scientists working for petitioner discovered that, in addition to its IOP-lowering effects, brimonidine can be used to protect optic nerve cells from dying—*i.e.*, that the drug has neuroprotective qualities. This ground-breaking new use for brimonidine is claimed in the two patents at issue in this suit. Since this discovery, the use of brimonidine as a neuroprotective agent has been widely publicized and accepted by many doctors. As a result, doctors now prescribe brimonidine for its neuroprotective use, and petitioner and others are funding ongoing research to prove the efficacy of brimonidine's neuroprotective use in humans.

D. Petitioner's Infringement Claims

In October, 2001, respondents filed ANDAs with the FDA seeking approval of generic brimonidine. Although there are already dozens of IOP-lowering drugs on the market, including several sold by respondents themselves, their ANDAs sought FDA approval only for brimonidine's use in lowering IOP. Respondents were fully aware, however, that, because large percentages of open-angle glaucoma patients have either normal IOP or do not respond to IOP-lowering treatment, the vast majority of glaucoma patients are candidates for neuroprotective treatment, and that respondents' generic versions of brimonidine can and will be used for the unapproved neuroprotective use claimed in petitioner's patent. In fact, respondents had already taken steps to encourage this use of brimonidine at the time they filed their ANDAs.

Thus, Alcon's website advertises neuroprotection as a glaucoma treatment, both as a general matter and with respect to one of its existing products, which, like petitioner's product, is indicated for use "in lowering intraocular pressure." In addition, Alcon's website lists articles that specifically discuss brimonidine's ability to protect the optic nerve. Similarly, respondent B&L's website promotes brimonidine as a neuroprotective drug to doctors. Through its Center for Contact Lens Research website, B&L distributes to doctors and other eye care professionals research by the one of the named inventors of petitioner's patents regarding brimonidine's neuroprotective effects. This research is presented with B&L's logo prominently displayed and without reference to petitioner, which paid for the research. The website also contains other abstracts on neuroprotection.

Based on the foregoing conduct and the submission of their ANDAs, petitioner sued respondents under § 271(e)(2). Petitioner alleged that, if the FDA approves the ANDAs, respondents will induce infringement of petitioner's patented methods of using brimonidine for neuroprotection.

E. The District Court's Decision

Alcon moved for summary judgment at the very outset of the case, arguing that it could not be liable under § 271(e)(2) because its ANDA sought approval only for use of brimonidine in the reduction of IOP, not the neuroprotective use claimed in petitioner's patents. The district court acknowledged that the record was "sufficient to present a triable issue of fact" concerning Alcon's direct or induced infringement, "or at the least, [to] allow [petitioner] to conduct discovery," App. 53a, and that § 271(e)(2) appeared, by its plain terms, "to address precisely the situation now before the Court." *Id.* at 54a. Nevertheless, the court concluded that "the structure of the Hatch-Waxman Act, its legislative history, and the specific problem that Section 271(e) was meant to address" overrode the statute's plain language. *Id.* at 60a.

In particular, the district court gave dispositive weight to a House Report describing the Act's certification provisions. Although the Act itself requires a certification "with respect to each patent which claims . . . a use for [the] listed drug," 21 U.S.C. § 355(j)(2)(A)(vii), the court believed that the House Report "set forth the process more clearly," App. 61a, and required a certification only for a patent that claimed the same use for which an ANDA applicant seeks FDA approval. *Id.* at 61a-62a. Based on this view of the certification provision, the court held that Congress did not authorize infringement actions where an ANDA does not seek FDA approval of the use claimed in a patent. *Id.* at 63a.

The court also concluded that § 271(e)(2) did not authorize a suit for inducing infringement. It reasoned that the claims that accrue upon the filing of an ANDA are limited to those that would have accrued earlier, but for the "testing" safe harbor created by subsection (e)(1). *Id.* at 63a-64a. The court also opined that future acts of induced infringement were not "sufficiently immediate" to satisfy Article III's "case or controversy" requirement. *Id.* at 66a.[1]

F. The Disposition of Petitioner's Appeal

The court below affirmed. The panel began by rejecting certain jurisdictional theories advanced by respondents or the district court. The panel explained that, by defining the submission of an ANDA as an act of infringement, the statute creates a case or controversy as soon as an ANDA is filed. *Id.* at 14a. While a § 271(e)(2) action for induced infringement depends on future infringing acts, such claims are not so speculative that they contravene Article III. *Id.* at 16a-17a. Summary judgment is thus inappropriate where, as here, a patentee has raised "a genuine issue of material fact

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[1] Respondent B&L filed a summary judgment motion that adopted Alcon's motion *in toto* and also raised additional factual arguments. In granting that motion, the district court relied on its ruling on Alcon's motion and declined to consider the additional issues B&L raised.

with respect to the claim that the ANDA filer will induce infringement of its patent upon approval of the ANDA." *Id.* at 17a. Turning to the merits of this case, however, the panel concluded that it was bound by the decision in *Warner-Lambert*, which held that § 271(e)(2) does not permit an action for induced infringement when the ANDA applicant does not seek FDA approval for the use claimed in the patent.

In rendering that decision, the *Warner-Lambert* panel stated that the statutory language making it an act of infringement to submit an ANDA for a drug "the use of which is claimed in a patent," "is most reasonably interpreted to mean 'the use *listed in the ANDA*.'" 316 F.3d at 1355-56 (emphasis added). It concluded that these additional words could be implied because the statute "recites 'a drug . . . *the* use of which is claimed,'" not a drug "'*a* use of which is claimed,'"or "'*any* use of which is claimed.'" *Id.* (emphasis and elipses in original). The *Warner-Lambert* panel believed that this reading was more consistent with what it perceived to be the purposes of the Act. The *Warner-Lambert* panel feared that an NDA holder could maintain its marketing exclusivity "by regularly filing a new patent application claiming a narrow method of use not covered by its NDA," then using that patent as a "sword" against any competitor's ANDA—a result that would "not advance the purpose of making available 'more low cost generic drugs.'" *Id.* at 1359.

The *Warner-Lambert* panel also based its interpretation on the House Report. The Report referred to "'*controlling use* patents,'" which it defined as use patents "'which claim an indication for the drug for which the applicant *is seeking approval*,'" and stated that an ANDA applicant "'may certify if applicable that one or more of the product or *controlling use* patents are invalid or will not be infringed.'" *Id.* (quoting H.R. Rep. No. 98-857, pt. 1, at 22, *reprinted in* 1984 U.S.C.C.A.N. at 2655 (emphases added by the panel)). According to the *Warner-Lambert* panel, this language from the House Report demonstrates that an ANDA applicant is

required to certify only with respect to a patent that claims the use for which the applicant seeks approval. *Id.* at 1360. This reading of the certification provision, the *Warner-Lambert* panel believed, confirmed its interpretation of § 271(e)(2).

Although bound by this precedent, the panel below nevertheless took the extraordinary step of writing to explain why *Warner-Lambert* was wrongly decided. Judge Schall, joined by Judge Clevenger, explained that, by defining the act of infringement as the filing of an ANDA for a drug "the use of which is claimed in a patent," Congress made clear that the relevant use is not "the use[] stated in the ANDA," but that "claimed in the patent." App. 23a. The fact that Congress used the phrase "controlling use patent" in the legislative reports but not in the statute demonstrated that Congress understood the concept, but "declined to employ that concept when it wrote section 271(e)(2)." *Id.* at 24a. Judge Schall explained that the only difference between an infringement action where the patented method of use is the subject of the ANDA, and one where the patented method of use is not the subject of the ANDA, "is the degree of proof required" to prove infringement. *Id.* at 25a. He found that petitioner's allegations concerning respondents' promotion of brimonidine for neuroprotection were sufficient to state a valid cause of action for induced infringement. *Id.* at 26a. He then explained why the various other provisions of the Hatch-Waxman Act that the *Warner-Lambert* panel cited cast no doubt on § 271(e)(2)'s plain meaning. *Id.* at 28a-38a.

In a separate concurrence, Judge Linn stated that the *Warner-Lambert* panel had improperly allowed its policy preferences to "override the terms of the statute chosen by Congress." *Id.* at 42a. That panel's fear that NDA holders might use method of use patents as swords against ANDA applicants did not justify "read[ing] the words 'the use for which the FDA has granted an NDA' into the statute." *Id.* at 43a. Because there is no indication that the plain language of § 271(e)(2) "does not reflect [Congress's] intent as to the

policy governing applications by generic drug manufacturers to produce drugs that may have patented 'off-label' uses," Judge Linn, too, would have interpreted the statute in accordance with Judge Schall's analysis. *Id.* 44a.

Despite the unanimous and cogent criticism of the *Warner-Lambert* decision by the panel below, the Federal Circuit denied en banc review without explanation.

REASONS FOR GRANTING THE PETITION

The proper interpretation of § 271(e)(2) is an extremely important issue, not only to pioneer and generic drug manufacturers, but to physicians and patients as well. Patent protection is essential to fostering the research and development that leads both to the introduction of new drugs and to breakthrough therapies that use existing medicines in new ways. The Federal Circuit's controlling interpretation of § 271(e)(2), however, essentially destroys patent protection for the latter innovations. By foreclosing pre-ANDA approval infringement actions for patents that claim "off-label" or subsequently approved uses of existing drugs, the Federal Circuit's interpretation of § 271(e)(2) prevents pioneers who develop innovative new uses from recouping the significant investments that underlie such therapeutic breakthroughs. Such postponed litigation can also disrupt medical care and treatment, by creating the risk that generic drugs will be withdrawn from the market after patients have begun using them. Although as a practical matter the Federal Circuit's exclusive jurisdiction precludes the possibility of a circuit split, the extraordinary criticism of the *Warner-Lambert* panel's binding interpretation by all members of the panel below vividly underscores the importance of the issue presented.

Those criticisms, moreover, were well founded. By adding a limiting qualification that appears nowhere in § 271(e)(2) itself, the *Warner-Lambert* panel interpreted the statute in a

manner that is flatly inconsistent with its plain language, its structure and its purpose. None of the rationales the *Warner-Lambert* panel offered—which reflect misconceptions concerning the statute's goals or misuse of its legislative history—justify this erroneous interpretation.

I. PROPER INTERPRETATION OF § 271(e)(2) IS A QUESTION OF EXCEPTIONAL IMPORTANCE TO THE PUBLIC HEALTH AND SAFETY.

The *Warner-Lambert* panel's interpretation of § 271(e)(2) has profound implications for the public health and safety. The *Warner-Lambert* decision denies meaningful patent protection to all owners of method of use patents that claim "off-label" methods of using drugs or that claim an FDA-approved use of any drug that has multiple approved uses. Unless overturned, this interpretation of the statute will significantly impede innovation in the pharmaceutical industry.

A. The Federal Circuit's Controlling Interpretation Of § 271(e)(2) Severely Undermines Financial Incentives For Developing Important New Uses For Existing Drugs And Could Disrupt Patient Care.

A critical aspect of present-day pharmaceutical research is the discovery of new uses for known drugs. Examples of such new uses often make headline news, and result in life-saving and/or life-improving treatments for millions of patients around the nation and the world.[2] As the widespread practice of "off-label" use makes clear, these important new uses "are often discovered after the FDA approves" NDAs for those drugs. See Beck & Azari, *supra* at 79. This is the case because research into these new uses is often prompted by the initial approval of a drug, where clinical safety is established.

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[2] *See e.g.*, Ron Winslow, *Arthritis Drug Celebrex Shows Promise as a Cancer Weapon, The Wall Street Journal* (May 22, 2002), at B1.

Regardless of when they are discovered, these new uses are the future of modern medicine. Due to the enormous expense and time required to develop and obtain approval of new drugs,[3] FDA approval of new molecular entities, or "blockbuster compounds," has been steadily declining, dropping from more than 30 approvals in the late 1990s to only 17 in 2002. Moreover, the majority of these new entities had similar therapeutic qualities to existing drugs or were relatives of previously discovered entities. Thus, "many therapeutic advances result from new uses of already-approved drug compounds or new dosage forms for existing drugs." James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 Cath. U. L. Rev. 433, 481-84 (1986); see also *Eli Lilly & Co.* v. *Generix Drug Sales, Inc.*, 460 F.2d 1096, 1103 (5th Cir. 1972) ("novelty, usefulness and non-obviousness inhere in the true discovery that a chemical compound exhibits a new needed medicinal capability.").

Like petitioner's investigation into the neuroprotective properties of brimonidine, many breakthroughs come from expensive and time-consuming research and development efforts by pioneer manufacturers. Because all drugs "have medical risks," Beck & Azari, *supra* at 72, pioneer manufacturers must perform the same careful studies, and incur many of the same expenses, to develop new uses for FDA-approved drugs as they do to develop and obtain NDAs for new drugs. In this case, for example, petitioner has spent approximately 10 to 15 million dollars researching brimonidine's neuroprotective uses.

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[3] In 2003, the estimated cost for pioneer drug manufacturers to bring new market was over $800 million and took 12 to 15 years. *See* K. I. Kaitin, *Tufts Center for the Study of Drug Development Impact Report* 2003 May/June 5(3).

Pioneer drug manufacturers simply cannot afford to make the substantial investments necessary to develop new uses of drugs if generic versions can enter the market based on FDA approval of an unpatented use. Because manufacturers of generic drugs invest very little in research and development, their products enter the market at dramatically reduced prices. And, because insurance companies, drug formularies and many state laws mandate substitution of generic drugs for pioneer products—regardless of the uses for which the generic was approved—entry of a generic almost immediately eliminates the profit margins that pioneers need to recoup their research and development costs. "The typical steep price decline upon generic entry results in an enormous drop in market share and profits for the pioneer firm," FTC, Prepared Statement Before the Senate Comm. on the Judiciary, *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements,* (May 24, 2001),[4] sometimes as much as 75% in just three months. See Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 Food & Drug L.J. 187, 191 (1999) (citing market share loss Syntax suffered three months after Naprosene (R) went off-patent); see also Cong. Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998), at chp. 3 (finding that pioneers lose 40% of their market on average to generics after patent expiration).

For a variety of reasons, an infringement action brought *after* an FDA-approved generic enters the market does not provide the protection necessary for an innovator to recoup its significant costs. The crucial remedy of a preliminary injunction is illusory at best. First, courts are extremely unlikely to prohibit all market access to a product that has non-infringing uses. See Wheaton, *supra*, at 482. Second,

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[4] Available at http:// www.ftc.gov/os/2001/05/pharmtstmy.htm.

the risk of harm to patients and the public interest will almost always weigh heavily against such relief—as courts have held in infringement cases involving medical devices.[5]

Nor does a damages remedy provide the assurance of recovery necessary to foster innovative new uses of drugs. Because of the typically large discrepancy between the price of pioneer drugs and their generic counterparts, lost profits damages will often be higher than the gross sales of the generic. And because generic manufacturers do not need to raise large amounts of capital and conduct expensive and time-consuming research and development, most lack sufficient assets to restore the lost profits that the pioneer patentee needs to recoup its research and development costs.

Permitting a generic drug to enter the market before infringement issues are resolved, moreover, deprives the pioneer of any economic incentive to conduct the safety and efficacy testing necessary to obtain an NDA for the patented use. If a pioneer conducted such tests, an NDA for the new use would confer on the pioneer, at most, the exclusive right to *label* its product for the new use for a three-year period.

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[5] *See, e.g., Neuromedical Systems, Inc.* v. *Neopath, Inc.*, 1998 WL 264845, at *16 (S.D.N.Y. May 26, 1998) (denying, in case involving medical device, motion for preliminary injunction based, in part, on finding that public interest would be harmed by injunction); *Ethicon Endo-Surgery* v. *U.S. Surgical Corp.*, 855 F. Supp. 1500, 1517 (S.D. Ohio 1994) (denying, in part on public interest grounds, preliminary injunction seeking to enjoin sale of surgical cutter); *GenDerm Corp.* v. *Ferndale Labs., Inc.*, 32 USPQ2d 1567, 1578-79 (E.D. Mich. 1994) (denying, in part on public interest grounds, preliminary injunction seeking to enjoin sale of topical cream); *Hybritech Inc.* v. *Abbott Labs.*, 4 USPQ2d 1001, 1003-04, 1014-15 (C.D. Cal.1987) (denying in part preliminary injunction: "Whatever else the court does, it will not cut off the supply of monoclonal test kits for cancer patients who are now using the Abbott product."), *aff'd*, 849 F.2d 1446 (Fed. Cir.1988); *cf. Reedco, Inc.* v. *Hoffman-La Roche, Inc.*, 667 F. Supp. 1072, 1081 (D.N.J. 1987) (denying, in part on public interest grounds, preliminary injunction seeking to enjoin sale of psoriasis treatment in trademark infringement case).

See 21 U.S.C. § 505(c)(3)(D)(iii). This "exclusive" labeling right, however, is meaningless where a generic version of the drug has already entered the market. Before the NDA for the new use ever issues (and the pioneer is granted its exclusive labeling rights), physicians will have already begun prescribing the generic for the patented new use. The economic demands of patients, insurers, formularies and even state laws ensure that physicians will continue to prescribe generic drugs for the new use after the pioneer obtains its exclusive labeling rights.

Finally, in addition to destroying the economic incentives necessary to spur innovative new uses of existing drugs, the *Warner-Lambert* panel's interpretation of § 271(e)(2) threatens future disruptions of patient care. Although courts likely will not enjoin generic drug sales during the pendency of an infringement action, once infringement of a patent is established, an injunction is ordinarily granted as a matter of course. See Donald S. Chisum, *Chisum on Patents* § 20.04[2] & n.1 (1999) (citing cases). Indeed, the very essence of a patent is the right to exclude others from its use. See 35 U.S.C. § 154(a)(1). Accordingly, generic manufacturers may be forced to withdraw their products after patients have begun using them. Cf. *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 106 F. Supp. 2d 696, 704-07 (D.N.J. 2000) (dismissing assorted public interest-based arguments and entering permanent injunction against future sales of veterinary drug). Changing prescriptions as a result of a withdrawal of a drug from the market can often be challenging to doctors and patients, particularly where it requires alterations in dosage levels and changes to other medications Obviously, these adverse effects will fall more heavily on the poor and elderly.

The Hatch-Waxman Act's patent-related provisions were plainly designed to prevent the foregoing problems. Those provisions ensure that a generic drug covered by a valid method of use patent does not reach the market until *after* the

patent expires, and that any dispute over whether a generic is covered by such a patent is resolved *before* the FDA approves the drug.[6] The Federal Circuit's interpretation of § 271(e)(2) destroys this careful design for all patents claiming "off-label" methods of use, as well as patents that claim only one of several FDA-approved uses for a drug. By doing so, the decision below will chill investment in the research and development necessary to promote innovative new uses of existing drugs—to the ultimate detriment of the nation's health. In short, the proper interpretation of § 271(e)(2) is an exceptionally important question requiring this Court's review.

B. The Concurring Opinions Below Confirm The Importance Of The Issue Presented.

The extraordinary concurring opinions below underscore the importance of the issue presented and the need for this Court's review. Because the Federal Circuit has exclusive jurisdiction over patent appeals, 28 U.S.C. § 1295(a), as a practical matter there can never be a split of authority among the circuits over the proper interpretation of § 271(e)(2). Nevertheless, this Court has granted review of several recent decisions where, as here, the Federal Circuit's dispositive resolution of an important issue of patent law spawned pointed dissents. See, *e.g.*, *Festo Corp.* v. *Shoketsu Kinzoko Kogyo Kabushiki Co.*, 535 U.S. 722, 730 (2002) (noting four dissenting opinions from en banc decision); *Warner-*

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[6] Where an ANDA applicant does not dispute that its generic drug will infringe a valid patent, FDA approval of the ANDA cannot take effect prior to the expiration of the patent. 21 U.S.C. § 355(j)(2)(A)(vii)(III), 355(j)(5)(B)(ii). Where the applicant does contest the validity or scope of a patent, § 271(e)(2)'s "artificial" act of infringement allows courts to hear and resolve such disputes during the 30-month period that FDA approval of the ANDA is stayed. See *id.* § 355(j)(5)(B)(iii). If the patent is found to be infringed and not invalid during that 30-month period, FDA approval of the drug likewise cannot take effect prior to the patent's expiration. *See id.* § 355(j)(5)(B)(iii)(III); 35 U.S.C. § 271(e)(4).

Jenkinson Co. v. *Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997) (noting "significant disagreement within" the Federal Circuit in en banc proceeding). Although the Federal Circuit declined to grant en banc review in this case, three judges exhaustively detailed the numerous analytical flaws in the now controlling interpretation of § 271(e)(2) that the *Warner-Lambert* panel rendered.

In addition, the Federal Trade Commission criticized the essentially identical interpretation that the district court rendered in this case. In a study of the drug industry, the FTC opined that the district court's dismissal of Allergan's case was erroneous and should be reversed. The FTC explained that

> "[u]nder the plain language of 35 U.S.C. § 271(e)(2), . . . *all* ANDAs constitute acts of infringement sufficient to establish the existence of a case or controversy with respect to *all* patents that claim any drug or any method of using the drug that may be infringed by generic marketing under an ANDA . . . ."

FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002).[7]

Finally, the judges on the panel below recognized that the *Warner-Lambert* panel's erroneous interpretation frustrates Congress's evident desire to have patent disputes resolved before the FDA approves an ANDA, and deprives both pioneer and generic manufacturers of the important benefits that such pre-approval resolutions provide. As Judge Schall explained, interpreting § 271(e)(2) to permit infringement claims even where the ANDA does not seek FDA approval for the patented method of use

> would benefit both the ANDA applicant and the patentee. The ANDA applicant would benefit by

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[7] Available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

> challenging the scope of a patentee's rights before the patent expires and before the applicant has invested in production and manufacturing facilities in reliance on its approved ANDA. The patentee, in turn, would profit by enforcing its patent rights before a generic drug manufacturer has moved into the market as a competitor. This balance is what Congress intended when it created the artificial act of infringement under section 271(e)(2).

App. 26a-27A; see also *id.* at 44a (Linn, concurring) (recognizing "[t]he importance of this issue").

The legal issue raised in this case thus has profoundly important implications for the public health and safety, and has generated sharp divisions between judges of the Federal Circuit. That issue thus warrants this Court's plenary review.

II. THE FEDERAL CIRCUIT'S CONTROLLING INTERPRETATION OF § 271(e)(2) IS WRONG.

The *Warner-Lambert* panel's interpretation of § 271(e)(2) not only undermines the financial incentives essential to the development of innovative new uses of existing drugs, it flatly contravenes congressional intent. By its plain terms, § 271(e)(2) permits precisely the type of pre-ANDA approval patent litigation that petitioner sought to institute in this case. None of the *Warner-Lambert* panel's rationales for ignoring this plain language withstands scrutiny.

A. The *Warner-Lambert* Panel's Interpretation Is Inconsistent With The Statute's Plain Language.

Section 271(e)(2) makes it an act of infringement to submit an ANDA

> for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submssion is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2). In both *Warner-Lambert* and this case, defendants submitted ANDAs for "a drug . . . the use of which is claimed in a patent" that had not expired. The *Warner-Lambert* panel concluded, however, that the statutory phrase "'the use' is most reasonably interpreted to mean 'the use listed in the ANDA.'" 316 F.3d at 1356. Thus, as construed by the *Warner-Lambert* panel, § 271(e)(2) makes it an act of infringement to submit an ANDA "for a drug . . . the use of which is claimed in a patent *and is listed in the ANDA*."

The *Warner-Lambert* panel sought to justify its undisguised amendment of the statutory language by placing critical weight on the statute's use of the definite article "the" before the word "use." It reasoned that, because § 271(e)(2) refers to a drug "'*the* use of which,'" rather than "'*a* use of which'" or "'*any* use of which'" is claimed in a patent, the words "'the use' require antecedent basis; thus, 'the use' refers to a specific 'use' rather than a previously undefined 'use.'" *Id.* (emphases in original). This reasoning is demonstrably wrong.

Congress plainly knew how to distinguish between (1) a use that is patented and (2) a use that is patented *and the subject of FDA approval*. In authorizing extensions for patents on FDA approved drugs or methods of using drugs, Congress provided that the rights derived from any such extension shall, "in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent *and approved for the product*." 35 U.S.C. § 156(b)(2) (emphasis added). Similarly, where an NDA holder lists a patent claiming a method of using the drug, an ANDA submitted for that drug must include a statement that the patent "does not claim a use *for which the applicant is seeking approval*." 21 U.S.C. § 355(j)(2)(A)(viii) (emphasis added). The fact that, in two separate provisions, Congress specified uses that are both patented *and* that are the subject (or not the subject) of FDA approval is fatal to any attempt to

read the additional qualification of an "approved" use into § 271(e)(2).[8] See, *e.g.*, *Russello v. United States*, 464 U.S. 16, 23 (1983) ("when one statutory section includes particular language that is omitted in another section of the same Act, it is presumed that Congress acted intentionally and purposely").

In short, the *Warner-Lambert* panel's interpretation of § 271(e)(2) is inconsistent with—indeed, it adds words to—the plain language of the statute. This clear judicial amendment of statutory language is yet another reason justifying plenary review by this Court. See *Pfaff* v. *Wells Elects., Inc.*, 525 U.S. 55, 60 (1998) (granting certiorari, in part, because the text of the statute the Federal Circuit had interpreted "ma[de] no reference to" the "'substantial completion' of an invention" test that the lower court applied).

B. Interpreting § 271(e)(2) In Accordance With Its Plain Terms Is Consistent With Congressional Intent.

Nor is there any merit to the *Warner-Lambert* panel's conclusion that the plain meaning of § 271(e)(2) is inconsistent with the purposes of the Hatch-Waxman Act. 316 F.3d at 1359. The panel based that conclusion on its mistaken view that an NDA holder "would be able to maintain its exclusivity merely by regularly filing a new patent application claiming a narrow method of use not

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[8] In reaching its contrary conclusion, the *Warner-Lambert* panel cited Justice Scalia's reliance on the word "the" in Article II, Section 2 of the Constitution "as narrowing a class to specific 'envisioned' members of the class." 316 F.3d at 1356 (quoting *Freytag* v. *Commissioner*, 501 U.S. 868, 902 (1991) (Scalia, J., concurring)). Justice Scalia emphasized, however, that the Constitution does not "'partake of the prolixity of a legal code,'" *Freytag*, 501 U.S. at 902 (quoting *McCulloch* v. *Maryland*, 17 U.S. (4 Wheat.) 316, 407 (1819)). The Hatch-Waxman Act, by contrast, is a legal code of great prolixity that does "bristle" with "explicit cross-reference[s]," *id.*, to numerous subsections and carefully defined concepts.

covered by its NDA," then "us[ing] § 271(e)(2)(A) as a sword against any competitor's ANDA seeking approval to market an off-patent drug for an approved use not covered by the patent." *Id.* Interpreting § 271(e)(2) in accordance with its plain terms, however, does not give rise to such a threat.

In suggesting otherwise, the *Warner-Lambert* panel failed to recognize that an allegation that a manufacturer has filed an ANDA for a drug "the use of which is claimed in a patent" is a necessary, but not a sufficient, predicate to a viable claim of induced infringement. To prevail on such a claim, the patentee must also establish that, "if the drug were approved based upon the ANDA, the manufacture, use, or sale of that drug would infringe the patent in the conventional sense." *Glaxo, Inc.* v. *Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). The patentee must therefore be able to allege, and ultimately prove, not only that an ANDA has been filed for a drug the use of which is claimed in its patent, but also that the applicant's drug will in fact be sold for the patented use because the applicant is encouraging or inducing the patented use or the patented use is the substantial use for the drug. Thus, only an NDA holder that obtains a patent on an unapproved use that has significant applications and utility will have a viable claim under § 271(e)(2).

Protecting patentees that develop commercially important innovative new uses for existing drugs is fully consistent with the purposes of the Act. Contrary to the view of the *Warner-Lambert* panel, see 316 F.3d at 1358, Congress's efforts to foster innovation in the pharmaceutical industry did not begin and end with the restoration of patent protection lost as a result of the lengthy FDA approval process. Rather, the carefully structured patent-related provisions of the Hatch-Waxman Act make clear that Congress also sought to ensure that generic drug competition did not destroy the financial incentives that pioneer manufacturers need to develop new drugs and new uses for existing drug. See *supra* at 18-19 & n.6; see also *Glaxo, Inc.* v. *Novopharm, Ltd.*, 110 F.3d at

1568 (explaining that the Act confers "benefits" on patentees "aside from patent term extension").

The *Warner-Lambert* panel was also plainly wrong in suggesting that pioneer companies that develop new uses for existing drugs make no investment worthy of protection unless and until they conduct the tests necessary to obtain FDA approval of such uses. 316 F.3d at 1359. As noted above, pioneers frequently spend significant amounts of money researching and developing new uses for existing drugs before they begin the studies required for FDA approval of an NDA. See *supra* at 15. The *Warner-Lambert* panel's construction of § 271(e)(2) ensures that such innovators will not have any incentive to make the further investments of time and money necessary to obtain FDA approval of their innovative new use. See *id.* at 15-18.[9]

In addition to denigrating the importance of, and the significant investments that underlie, patents on "off-label" methods of use, the *Warner-Lambert* completely ignored the fact that, in many instances, pioneers obtain patents on one of several FDA-approved uses. It is not uncommon, for example, for a pioneer to obtain a patent and an NDA on an initial use, and then later to obtain an NDA and patent on a second use. In such circumstances, when the patent on the first approved use expires, a generic manufacturer can submit an ANDA for that use and, under the *Warner-Lambert* panel's misconstruction of § 271(e)(2), its generic drug can enter the market and be prescribed for the second, still patented, FDA-approved use. Thus, foreclosing actions under § 271(e)(2) when an ANDA does not seek approval of a patented method of use destroys investments that even the *Warner-Lambert* panel deemed worthy of protection.

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[9] In all events, the exclusive rights that the Patent Act confers do not depend on the amount of money and time spent on research, but on the development of a useful, novel and non-obvious invention.

C. The Patent Certification Provision And Its Legislative History Do not Override The Plain Language Of § 271(e)(2).

Finally, in justifying its interpretation of § 271(e)(2), the *Warner-Lambert* panel placed great weight on the patent certification provision and its legislative history. As noted above, that provision requires a certification:

> with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug *for which the applicant is seeking approval* under this subsection and for which information is required to be filed under subsection (b) or (c) of this section."

21 U.S.C. § 355(j)(2)(A)(vii) (emphasis added). The *Warner-Lambert* panel concluded that the highlighted phrase modifies the word "use," and thereby confirms that § 271(e)(2) applies only when a method of use claim covers the use for which the ANDA filer seeks FDA approval.

The panel's conclusion in this regard is plainly mistaken. First, as Judge Schall explained in his concurring opinion below, App 34a-35a, the certification provision contains two parallel "for which" clauses—"for which the applicant is seeking approval . . . and for which information is required to be filed under subsection (b) or (c)"—both of which necessarily modify the same antecedent. The antecedent for the second clause, however, can only be the "listed drug." Subsection (b) requires the NDA applicant to file certain information concerning "any patent which claims the drug . . . or which claims a method of using such drug." 21 U.S.C. § 355(b)(1). Subsection (c), in turn, refers to "the patent information described in subsection (b)." *Id.* § 355(c)(2). Neither subsection contains an antecedent for "information" that the NDA applicant must file concerning the "use" for which approval is sought. Indeed, the ANDA provisions confirm that the antecedent for the "information" identified in

the second "for which" clause is patent information about the "listed drug." Immediately after the certification provision, subsection (viii) requires a separate statement "if *with respect to the listed drug . . . information was filed* under subsection (b) or (c) of this section for a method of use patent." *Id.* § 355(j)(2)(A)(viii) (emphasis added).

Second, the combination of the certification provision and subsection (viii) refute the *Warner-Lambert* panel's narrow construction of § 271(e)(2). Together, these provisions require one of four certifications *and*, where applicable, a separate statement concerning a method of use patent. Thus, for each patent "which claims the listed drug . . . or which claims a use for such listed drug," the ANDA filer must make a certification

> (I) that such patent information has not been filed,
>
> (II) that such patent has expired,
>
> (III) of the date on which such patent will expire, *or*
>
> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; *and*
>
> (viii) if with respect to the listed drug . . . information was filed under subsection (b) or (c) of this section for a method of use patent *which does not claim a use for which the applicant is seeking approval under this subsection*, a statement that the method of use patent does not claim such a use.

Id. § 355(j)(2)(A)(vii)-(viii) (emphases added).

Congress's careful use of the disjunctive with respect to the required certifications and the conjunctive when introducing subsection (viii)'s separate statement requirement makes plain that, even when a listed patent claims a use for which the applicant is not seeking approval, the Act requires *both* a statement that the patent does not claim a use for which

ANDA approval is sought *and a paragraph (IV) certification of noninfringement and/or invalidity*. The fact that Congress required a certification with respect to a patent that claims a use other than the one for which the applicant seeks approval confirms that a § 271(e)(2) infringement action can be brought in such circumstances as well. Had it not intended to permit § 271(e)(2) actions based on patents that claim uses for which the ANDA applicant is not seeking approval, Congress would have required *only* the subsection (viii) statement in such circumstances, not such a statement and an appropriate certification as well.

Ignoring the clear import of these provisions, the *Warner-Lambert* panel relied instead on two passages from the House Report that accompanied the Hatch-Waxman Act. See 316 F.3d at 1359-60. In the first such passage, the House Report states that

> [w]ith respect to all product patents which claim the listed drug and all use patents which claim an indication for the drug *for which the applicant is seeking approval* (hereafter described as a *controlling use* patent), the applicant must certify, in his opinion and to the best of his knowledge, as to one of four circumstances.

H.R. Rep. No. 98-857, pt. 1, at 22, *reprinted in* 1984 U.S.C.C.A.N. at 2655 (emphases added). This legislative history, however, cannot override the plain language of § 271(e)(2) and the clear import of the certification provision and subsection (viii). See *Garcia* v. *United States*, 469 U.S. 70, 75 (1984) ("[O]nly the most extraordinary showing of contrary intentions from [the legislative history] would justify a limitation on the 'plain meaning' of the statutory language"). In fact, as Judge Schall explained, App. 36a-37a, this legislative history simply highlights the fact that Congress knew how to distinguish between patented uses and patented uses for which FDA approval is sought. The fact that Congress knew how to draw this distinction, did so in the legislative history (and, as noted above, in other provisions of

the Act), but did not do so in either § 271(e)(2) or the enacted language of the certification provision refutes, rather than supports, the *Warner-Lambert* panel's interpretation of these provisions.

That panel also relied on an example the House Report provided to illustrate how the certification provision would work. In this passage, the Report states

> [f]or example, the listed drug may be approved for two indications. If the applicant is seeking approval only for Indication No. 1, and not Indication No. 2 *because it is protected by a use patent*, then the applicant must make the appropriate certification and a statement explaining that it is not seeking approval for Indication No. 2.

H.R. Rep. No. 98-857, pt. 1, at 22, *reprinted in* 1984 U.S.C.C.A.N. at 2655 (emphases added). This passage *confirms* the clear import of subsection (vii)'s certification requirement and subsection (viii)'s statement requirement, and completely refutes the *Warner-Lambert* panel's construction of those subsections. By its plain terms, this passage from the House Report states that where a patent claims a use (or indication) for which the applicant does *not* seek FDA approval, the applicant must nevertheless still "make the appropriate certification *and* a statement explaining that it is not seeking approval for" the patented use. This passage, therefore, provides no basis for foreclosing § 271(e)(2) infringement actions when an ANDA does not seek FDA approval of a patented method of use.

In short, the *Warner-Lambert* panel's controlling construction of § 271(e)(2) is demonstrably wrong. It is inconsistent with the language, structure and purposes of the Hatch-Waxman Act, and will undermine patient health and safety by depriving pioneers of the financial incentives necessary to spur development of breakthrough new uses of existing drugs. This Court should grant a writ of certiorari to correct this important legal error.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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September 19, 2003

APPENDIX A

UNITED STATES COURT OF APPEALS
FEDERAL CIRCUIT

No. 02-1449

ALLERGAN, INC. AND ALLERGAN SALES, INC.,
Plaintiffs-Appellants,

v.

ALCON LABORATORIES, INC., ALCON RESEARCH, LTD.,
AND ALCON UNIVERSAL, LTD.,
Defendants-Appellees,

and

BAUSCH & LOMB, INCORPORATED,
Defendant-Appellee.

DECIDED: March 28, 2003.

Before CLEVENGER, SCHALL, and LINN, Circuit Judges.

Opinion concurring in the judgment filed by Circuit Judge SCHALL, in which Circuit Judge CLEVENGER joins.

Opinion concurring in the judgment filed by Circuit Judge LINN.

PER CURIAM.

This appeal presents the question of whether the Drug Price Competition and Patent Term Restoration Act of 1984, Pub.L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355 and 360cc and 35 U.S.C. §§ 156 and 271) (the

"Hatch-Waxman Act"), allows an action for induced infringement based upon the filing of an Abbreviated New Drug Application ("ANDA"), in the following circumstances: (i) The patent at issue claims a method of using a specified drug for a particular purpose, but that use has not been approved by the Food and Drug Administration ("FDA") based upon a New Drug Application ("NDA"), (ii) the ANDA applicant seeks approval for the production of a generic version of the drug for a use that is different from the method of use of the drug that is claimed in the patent; and (iii) the generic drug that is the subject of the ANDA is effective for the method of use that is claimed in the patent.

This question arises in the context of a suit by Allergan, Inc. and Allergan Sales, Inc. ("Allergan") against Alcon Laboratories, Inc., Alcon Research, Ltd., and Alcon Universal, Ltd. ("Alcon"), and Bausch & Lomb, Incorporated ("B & L") for infringement of United States Patent Nos. 6,194,415 (the "'415 Patent") and 6,248,741 (the "'741 Patent"). The '415 patent claims a method of protecting the optic nerve through the administration of the drug brimonidine, while the '741 patent claims a method of neural protection through the administration of brimonidine. Brimonidine itself is not patented, and the FDA has not approved brimonidine for the uses claimed in the '415 and '741 patents. However, brimonidine is effective for those uses.[1]

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[1] The FDA does not prohibit doctors from prescribing a drug for an unapproved or off-label use, and it does not prohibit patients from using a drug for an unapproved or off-label use. *See Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1356, 65 USPQ2d 1481, 1485 (Fed. Cir.2003) (stating that "a physician may prescribe an approved drug for any use consistent with acceptable medical practices . . . ."). Additionally, several states require doctors to prescribe a generic version of a drug, if available, for all approved and unapproved uses for which the drug is prescribed. *See, e.g.*, N.Y. Educ. Law § 6810(6)(a) (2002).

Allergan initiated suit in the United States District Court for the Central District of California after Alcon and B & L submitted ANDAs to the FDA seeking approval for the production and sale of a generic version of brimonidine for the reduction of intraocular pressure, a use different from the uses for brimonidine claimed in the '415 and '741 patents. Allergan charged Alcon and B & L with induced infringement under the authority of 35 U.S.C. § 271(e)(2).[2] In due course, Alcon and B & L filed motions for summary judgment of non-infringement, arguing that a claim of induced infringement is not cognizable under section 271(e)(2) where, as here, the ANDA is for a use of the drug that is different from the use of the drug that is claimed in the asserted patent. The district court agreed. Accordingly, it granted Alcon's and B & L's motions, dismissed Alcon's and B & L's non-infringement and invalidity counterclaims without prejudice, and certified the case pursuant to Fed.R.Civ.P. 54(b). *Allergan, Inc. v. Alcon Labs., Inc.*, 200 F.Supp.2d 1219, 63 USPQ2d 1427 (C.D.Cal.2002); *Allergan, Inc. v. Alcon Labs., Inc.*, No. SA CV 02-40 DOC (ANx) (C.D. Cal. Jun 4, 2002).

Prior to January 16, 2003, the question presented in this case represented an issue of first impression. On that day, however, a panel of this court decided *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 65 USPQ2d 1481 (Fed.Cir. 2003). In *Warner-Lambert*, this court held that "it is not an act of infringement to submit an ANDA for approval to market a drug for a use when neither the drug nor the use is covered by an existing patent, and the patent at issue is for a use not approved under the NDA." *Warner-Lambert*, 316 F.3d at 1354-55, 65 USPQ2d at 1484. Based upon *Warner-Lambert*, we affirm the district court's decision that the action for induced infringement brought by Allergan is not cognizable under 35 U.S.C. § 271(e)(2).

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[2] All references are to statutes set forth in the 2000 version of the United States Code.

BACKGROUND

I. The Hatch-Waxman Act

We recently stated that, in the Hatch-Waxman Act, "Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371, 61 USPQ2d 1414, 1415 (Fed.Cir.2002). To accomplish the goals of the Act, Congress amended provisions of the patent statute and the Food, Drug, and Cosmetic Act ("FDCA").

Prior to the passage of the Act, all drug manufacturers, brand name and generic, had to perform controlled studies to demonstrate that a new drug would be safe and effective for its intended use.[3] This requirement resulted in long delays between the time when a brand name drug manufacturer received a patent for a new drug and the drug reached the market. It also resulted in long delays between the time when the patent expired and generic drug manufacturers were able to market a generic version of the drug. The Hatch-Waxman Act sought to address this situation by providing brand name drug manufacturers with limited extensions of their patent terms in order to restore a portion of the market exclusivity lost through the lengthy process of drug development and FDA approval. At the same time, to counter this benefit to the brand name manufacturers, the Act provided generic drug manufacturers with a patent infringement exemption for experimentation in connection with an application for FDA approval of a generic drug. It also provided a shortened FDA approval process for generic drugs. H.R.Rep. No. 98-857, pt.

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[3] The FDA previously allowed ANDAs for pioneer drugs approved prior to 1962. H.R.Rep. No. 98-857, pt. 1, at 16 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647-48.

1, at 14-15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647-48.

Before a drug manufacturer can market a new drug, it must obtain FDA approval. 21 U.S.C. § 355(a). The approval process requires the submission of a NDA, which is the result of extensive testing and which must include safety information, efficacy information, and composition data. 21 U.S.C. § 355(b). Pursuant to the Hatch-Waxman Act, the FDA, upon approval of a NDA, grants the applicant a five-year period of exclusive marketing for the approved drug, which can be extended by six months if the producer submits safety information relating to children. 21 U.S.C. §§ 355(c)(3)(D)(ii) and 355a(a)(1)(A)(i). This period of exclusivity was primarily designed by Congress to encourage the development and testing of unpatentable pharmaceuticals. H.R.Rep. No. 98-857, pt. 1, at 29 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647-48. The FDA approval process requires a NDA applicant to file with its NDA the following:

> the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

21 U.S.C. § 355(b)(1). The holder of an approved NDA must file the same information with respect to similar patents that are obtained after the NDA is approved. 21 U.S.C. § 355(c)(2). The FDA lists such patents in a book entitled "Ap-proved Drug Products with Therapeutic Equivalence Evaluations." The book is commonly referred to as the "Orange Book." *Andrx,* 276 F.3d at 1371, 61 USPQ2d at 1415.

To attain a balance between the interests of brand name pharmaceutical companies and generic drug manufacturers, Congress, as part of the Hatch-Waxman Act, legislated that a

generic drug manufacturer may, without liability for infringement, use a drug claimed in a patent or a method of using a drug claimed in a patent in order to prepare an application for FDA approval of a generic drug. 35 U.S.C. § 271(e)(1). At the same time, Congress extended the ANDA process to post-1962 pioneer drugs to couple with the NDA process. A generic drug manufacturer may file an ANDA to obtain approval for a generic drug. 21 U.S.C. § 355(j). The ANDA must be for the same drug that has been approved by the FDA, or it must be for a drug that is the bioequivalent of a drug that has been approved by the FDA. 21 U.S.C. § 355(j)(2).

The ANDA process imposes a certification requirement with respect to patents covering the drug that has been approved by the FDA. A generic drug manufacturer must certify in its ANDA the following with respect to each patent "which claims the [drug previously approved by the FDA] or which claims a use for [that] drug for which the applicant is seeking approval . . . and for which information is required to be filed" for listing in the Orange Book: (i) such patent information has not been filed; (ii) the approved drug's patent has expired; (iii) the date the approved drug's patent will expire; or (iv) the approved drug's patent "is invalid or will not be infringed by the manufacture, use, or sale" of the generic drug for which the ANDA is being submitted (a "Paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii); *see Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1244, 54 USPQ2d 1711, 1712 (Fed.Cir.2000). If a method of using the approved drug is patented and is listed in the Orange Book, but the manufacturer is not seeking approval for the patented use, the manufacturer must state in the ANDA that the method of use patent does not claim the use for which the manufacturer is seeking approval. 21 U.S.C. § 355(j)(2)(A)(viii).

As suggested by the certification process, a generic drug manufacturer may file an ANDA before a patent expires and, in so doing, allege non-infringement and invalidity of the patent.[4] The Hatch-Waxman Act provides that, in that situation, the filing of the ANDA is an act of infringement. 35 U.S.C. § 271(e)(2)(A); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568-69, 42 USPQ2d 1257, 1263 (Fed.Cir. 1997). The exemption to infringement under section 271(e)(1) allows a generic drug manufacturer to take the steps needed to bring a generic drug to market without waiting until the patent expires. At the same time, by deeming the filing of an ANDA to be an act of infringement under section 271(e)(2), the Hatch-Waxman Act allows a brand name drug manufacturer to challenge the ANDA application and a generic drug manufacturer to challenge the validity and infringement of an asserted patent before the patent expires. *Id.*

A generic drug manufacturer who files an ANDA containing a Paragraph IV certification must notify the owner of the unexpired patent that is the subject of the certification. 21 U.S.C. § 355(j)(2)(B)(i) & (ii). The patent owner then has 45 days to file an action for infringement in district court. 21 U.S.C. § 355(j)(5)(B)(iii). If suit is filed, the court then determines whether the applicant will, if the application is approved, infringe the patent at issue. *Glaxo*, 110 F.3d at 1569, 42 USPQ2d at 1263. If the patent owner does not file suit within the required time period, the ANDA may be approved immediately, subject to applicable FDA regulations. 21 U.S.C. § 355(j)(5)(B)(iii). If the patent owner files an infringement action, the ANDA may not be approved until the date the court determines invalidity or non-infringement,

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[4] A generic drug manufacturer may also file an ANDA after the corresponding NDA holder's fourth year of FDA granted market exclusivity ends, if the ANDA contains a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii). 21 U.S.C. § 355(j)(5)(D)(ii).

the date the patent expires, or 30 months from the date the patent holder receives notice of the ANDA Paragraph IV certification (subject to judicial discretion), whichever occurs first. *Id.*

II. The '415 and '741 Patents

This case arises out of Alcon's and B & L's efforts to market a generic version of Allergan's medication, Alphagan. Alphagan is used in the treatment of open-angle glaucoma, a disease of the eye that results in the deterioration of vision. Open-angle glaucoma is caused by damage to the optical cells, but it is unknown exactly how this damage occurs. For years, the accepted belief of the medical profession was that the disease was caused by exceptionally high intraocular pressure ("IOP"), resulting from a failure of the eye fluid, called aqueous humor, to properly drain. The high pressure in the eye presumably bore down on the optic nerve, thereby damaging it. Drug manufacturers sought pharmaceutical components that reduced IOP in the eye in order to treat glaucoma.

On September 6, 1996, Allergan obtained approval of its NDA for the drug, brimonidine, the chemical compound in Alphagan, for reducing IOP. As a result, Allergan received a five-year period of market exclusivity for brimonidine plus a six-month extension for researching the health effects and safety of the drug in children. This exclusive term expired on March 6, 2002. Brimonidine is not protected by a patent and is therefore in the public domain.

More recently, scientists have discovered that open-angle glaucoma also occurs in patients with low IOP. They therefore conjecture that it may be a neurodegenerative disease of the optic nerve. Upon further investigation, Allergan's scientists discovered that brimonidine helps prevent neurodegeneration. This discovery led Allergan to file for the '415 and '741 patents, each of which is a method of use patent. The

'415 and '741 patents do not claim the use of brimonidine for reducing IOP. That use, like the drug itself, is unpatented and in the public domain.

The '415 and the '741 patents claim methods of using brimonidine for treating ocular neural injuries, such as open-angle glaucoma. The '415 patent claims "[a] method of protecting the optic nerve and retina of a mammal comprising administering to said mammal suffering from or at risk of suffering a noxious action on said nerve cells an effective amount of [brimonidine] to inhibit or prevent nerve cell injury or death . . . ." '415 patent, col. 17, ll. 35-39, col. 18, ll. 1-25. The first dependent claim defines the noxious action as "glaucomatous optic neuropathy." '415 patent, col. 18, ll. 26-27. The '741 patent claims "[a] method of providing neural protection to a mammal comprising administering to said mammal suffering from or at risk of suffering a noxious action on its nerve cells an effective amount of [brimonidine] to inhibit or prevent nerve cell injury or death . . . ." '741 patent, col. 17, ll. 27-39, col. 18, ll. 1-8. The first dependent claim defines the noxious action as being "a result of a crushed or compressed nerve." '741 patent, col. 18, ll. 10-11. Both the '415 patent and the '741 patent are continuations-in-part of application number 08/496,262, now United States Patent No. 5,856,329 (the " '329 patent"). The '415 and '741 patents carry terminal disclaimers to the '329 patent. The '329 patent was filed on June 28, 1995. Therefore, due to the terminal disclaimers, all three patents expire on June 28, 2015. After the '415 and '741 patents issued in 2001, Allergan submitted information relating to the patents to the FDA so that they could be listed in the Orange Book.

III. Alcon's and B & L's ANDAs and Allergan's Lawsuit

In October of 2001, Alcon filed an ANDA for brimonidine, and in November of 2001, B & L filed one as well. In their ANDAs, Alcon and B & L stated that they were seeking approval from the FDA to produce and sell a generic version

of brimonidine for use in lowering IOP in patients with open-angle glaucoma or ocular hypertension. Neither Alcon nor B & L sought FDA approval for the methods of using brimonidine claimed in the '415 and '741 patents. As part of their respective ANDAs, Alcon and B & L filed Paragraph IV certifications, based on Allergan's Orange Book listings, indicating that Allergan's '415 and '741 patents were not infringed and that, to the extent Allergan asserted that the patents covered IOP lowering, they were invalid. After Alcon and B & L gave Allergan notice of the filing of their ANDAs for brimonidine, Allergan instituted suit against both companies in the United States District Court for the Central District of California within the 45 day time period set forth in 21 U.S.C. § 355(j)(5)(B)(iii). Allergan brought its suit under 35 U.S.C. § 271(e)(2), alleging that if the FDA approved Alcon's and B & L's ANDAs, Alcon and B & L would induce doctors to infringe the '415 and '741 patents by prescribing brimonidine for neuroprotection and would induce patients to infringe by using brimonidine for neuroprotection. Allergan also alleged that, through the submission of their ANDAs, Alcon and B & L were liable for infringement because they violated 35 U.S.C. § 271(e)(2) directly.

As noted above, Alcon and B & L moved for summary judgment of non-infringement, arguing that a claim of induced infringement is not cognizable under section 271(e)(2) where, as here, the ANDA is for a use of the drug that is different from the use of the drug that is claimed in the asserted patent. In ruling on the motions, the district court noted that, as far as Alcon was concerned, Allergan had presented sufficient evidence to present a triable issue of fact with regard to induced infringement, or had at least presented sufficient evidence to proceed to discovery.[5] *Allergan,* 200

[5] Responding to the summary judgment motions, Allergan presented evidence in the form of research papers, patents, and articles suggesting that the neuroprotective functions of brimonidine are well known in the

F.Supp.2d at 1225, 63 USPQ2d at 1431. The district court did not make a similar finding with respect to B & L. The district court, nevertheless, granted Alcon's and B & L's motions. Addressing Allergan's claim of induced infringement, the court held that the filing of an ANDA does not provide a predicate for a method of use patent holder to sue an ANDA applicant for induced infringement. *Id.* at 1232, 63 USPQ2d at 1437. The court viewed section 271(e)(2) as being symmetrical with section 271(e)(1), which, as noted above, allows a generic drug manufacturer to use a patented drug in order to prepare an application for FDA approval without liability for infringement. The court therefore reasoned that the type of claims that accrue upon the filing of an ANDA are limited to those claims that a patent holder could have brought in the absence of section 271(e)(1). The court stated that, had section 271(e)(1) not been enacted, Allergan could have sued Alcon for infringement for using its patent in the development of a generic drug. "It could not, however, sue Alcon for inducing infringement because there was yet to be any third-party infringement and thus the question of inducing infringement would be entirely too speculative." *Id.* at 1231, 63 USPQ2d at 1436. Under these circumstances, the district court concluded, "allowing a patentee to bring a claim for inducing infringement under [s]ection 271(e)(2) runs afoul of the 'case or controversy' requirement of Article III [of the Constitution]." *Id.* at 1232, 63 USPQ2d at 1437. The district court rejected Allergan's direct cause of action claim on the ground that section 271(e)(2) does not expand the traditional grounds of patent infringement; it requires the

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medical field and that doctors are currently prescribing brimonidine for neuroprotective purposes. In addition, Allergan submitted evidence of instances where Alcon allegedly advertised an ANDA approved drug for uses other than those uses approved by the FDA. Finally, Allergan presented evidence indicating that Alcon and B & L have included articles on their websites that discuss brimonidine's neuroprotective properties.

same inquiry as any other infringement suit. *Id.* at 1227, 63 USPQ2d at 1433.

Allergan now appeals the district court's grant of Alcon's and B & L's motions for summary judgment. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

I. Standard of Review

We review a grant of summary judgment by a district court *de novo*. *Cortland Line Co. v. Orvis Co.*, 203 F.3d 1351, 1355-56, 53 USPQ2d 1734, 1736 (Fed.Cir.2000). Summary judgment is appropriate where the record shows "that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. R. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). We review a district court's interpretation of statutory language, which is a question of law, without deference. *Waymark Corp. v. Porta Sys. Corp.*, 245 F.3d 1364, 1366, 58 USPQ2d 1456, 1458 (Fed.Cir.2001). In this case, the issue before us is a question of law: whether the district court erred in holding that the Hatch-Waxman Act does not support Allergan's claim of induced infringement against Alcon and B & L.

II. Contentions of the Parties

On appeal, Allergan argues that the district court erred in construing 35 U.S.C. § 271(e)(2) so as to bar suits for induced infringement. Allergan contends that Congress enacted section 271(e)(2) to complement the filing of an ANDA, not to counterbalance 35 U.S.C. § 271(e)(1). Allergan further argues that, pursuant to section 271(e)(2), it may bring a suit for induced infringement of the '451 and '741 patents, even though Alcon's and B & L's ANDAs do not seek approval for the methods of using brimonidine claimed in those patents. In the alternative, Allergan urges that section

271(e)(2) provides a direct cause of action that makes Alcon and B & L liable for direct infringement based upon the filing of their ANDAs.

Alcon responds that the district court properly granted summary judgment against Allergan. Alcon argues that Allergan's suit cannot succeed for two reasons. First, according to Alcon, section 271(e)(2) only provides jurisdiction for an action for infringement of a method of use patent when the patent at issue claims an FDA-approved use and the ANDA applicant is seeking approval for that use. Second, Alcon asserts that, under section 271(e)(2), the conventional requirements for infringement under 35 U.S.C. § 271(a), (b), and (c) apply and that, in this case, there is no direct infringement by a third party and no evidence that Alcon has or will actively promote its generic drug for an infringing use. B & L joins in Alcon's arguments. In addition, it contends that Allergan has not shown any triable issue of fact with respect to its claim of induced infringement against B & L.[6]

For the reasons that follow, we hold that *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 65 USPQ2d 1481 (Fed.Cir.2003), controls this case and that, under *Warner-Lambert*, Allergan may not sue Alcon and B & L under section 271(e)(2) for inducing infringement of the '415 and '741 patents. We therefore affirm the district court's grant of summary judgment in favor of Alcon and B & L.

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[6] The Washington Legal Foundation ("WLF") submitted an *amicus curiae* brief. WLF argues that the district court erred in ruling that Allergan's induced infringement claim does not present a case or controversy as required by Article III. WLF also argues that the plain language of section 271(e)(2) supports Allergan's contention that section 271(e)(2) allows its claim of induced infringement.

III. Whether 35 U.S.C. § 271(e)(2) is a Jurisdictional Statute

The district court stated that "[s]ection 271(e)(2) . . . provides no new substantive law, but much like the Declaratory Judgment Act, 28 U.S.C. § 2201, merely provides a jurisdictional 'hook' for a patent case." *Allergan*, 200 F.Supp.2d at 1227, 63 USPQ2d at 1433. On appeal, Alcon and B & L argue that section 271(e)(2) did not provide the district court with jurisdiction over Allergan's action because Allergan did not assert infringement of a method of use patent that claims an FDA-approved use for which Alcon and B & L are seeking FDA approval. Under these circumstances, we think it appropriate to address at the outset whether section 271(e)(2) is a jurisdictional statute.

Section 271(e)(2) is not a jurisdictional statute in the strict sense of the word. As the Supreme Court pointed out in *Eli Lilly Co. v. Medtronic, Inc.*, section 271(e)(2) creates an "act of infringement" based upon the filing of an ANDA. 496 U.S. 661, 678, 110 S.Ct. 2683, 110 L.Ed.2d 605, 15 USPQ2d 1121, 1130 (1990). We explained in *Glaxo* that section 271(e)(2) "provide[s] patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity." *Glaxo*, 110 F.3d at 1569, 42 USPQ2d at 1263. Once Congress creates an act of infringement, jurisdiction in the district court is proper under 28 U.S.C. § 1338(a). Section 1338(a) states that "[t]he district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents . . . ." Section 271(e)(2) is an Act of Congress relating to patents. Therefore, section 1338(a) provides for jurisdiction in the district court for Allergan's suit.

In short, section 271(e)(2) makes it possible for the district court to exercise its section 1338(a) jurisdiction in the situation in which an ANDA has been filed. The critical

question, and the one to which we now turn, is whether Allergan's claim of induced infringement against Alcon and B & L is cognizable under section 271(e)(2).

IV. Whether Allergan's Claim of Induced Infringement May be Brought Under 35 U.S.C. § 271(e)(2)

A. *Claims of Induced Infringement Under Section 271(e)(2) Generally*

Preliminarily, we must determine whether, as a general matter, section 271(e)(2) may serve as an umbrella for a claim of induced infringement for a method of use patent. As noted above, the district court concluded that it could not. The district court reasoned that the type of claims that accrue upon the filing of an ANDA are limited to those claims that a patent holder could have brought in the absence of section 271(e)(1), such as an infringement claim against a generic drug manufacturer for using the patent in the development of a generic drug. The district court determined that a claim of induced infringement, based upon conduct of a third party that would occur upon approval of an ANDA, was not a claim that a patent holder could have brought before the enactment of section 271(e)(1). *Allergan*, 200 F.Supp.2d at 1231, 63 USPQ2d at 1436. The district court concluded that "[s]ection 271(e)(2) . . . does not provide a predicate for Allergan to sue for inducing infringement." *Id.* at 1230, 63 USPQ2d at 1435.

We do not share the district court's view of 35 U.S.C. § 271(e)(2). To begin with, the language of section 271(e)(2) does not limit the reach of the statute to direct infringement actions to the exclusion of actions for induced infringement. Additionally, in *Glaxo*, we did not limit the scope of section 271(e)(2) to direct infringement actions. Instead, we stated that a court must employ a traditional infringement analysis, focusing on all of the elements of infringement. *Glaxo*, 110 F.3d at 1567, 42 USPQ2d at 1262 ("The plain language of the statute does not alter a patentee's burden of proving infringe-

ment . . . ."). The only difference in the analysis of a traditional infringement claim and a claim of infringement under section 271(e)(2) is the timeframe under which the elements of infringement are considered. *Id.* at 1569, 42 USPQ2d at 1263 ("[T]he question of infringement must focus on what the ANDA applicant will likely market if its application is approved . . . ."). *Glaxo* does not preclude patentees from asserting claims for induced infringement under 35 U.S.C. § 271(e)(2). In fact, a patent holder asserting infringement of a patent that claims a FDA-approved method of use for which an ANDA seeks approval will, in many instances, have to prove induced infringement. Therefore, section 271(e)(2) may support an action for induced infringement.

Finally, we do not agree with the district court that the "case or controversy" requirement of Article III of the Constitution precludes a patentee from bringing a claim of induced infringement under section 271(e)(2). The district court was of the view that, in the case of a claim of induced infringement predicated on direct infringement by third party physicians, there is "not a sufficiently immediate threat that there will be a violation of the patent laws so as to warrant judicial determination." *Allergan*, 200 F.Supp.2d at 1232, 63 USPQ2d at 1437.

The case or controversy clause in Article III of the Constitution requires injury in fact, connection between the challenged conduct and the injury, and redressability of the injury by the requested remedy. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103-04, 118 S.Ct. 1003, 140 L.Ed.2d 210 (1998) ("This triad of injury in fact, causation, and redressability comprises the core of Article III's case-or-controversy requirement . . . ."). A claim under 35 U.S.C. § 271(e)(2) is, by its very nature, speculative to a certain degree, as acknowledged in *Glaxo*. *See Glaxo*, 110 F.3d at 1569, 42 USPQ2d at 1263 ("The only difference in actions brought under § 271(e)(2) [from actions brought under

section 271(a)] is that the allegedly infringing drug has not yet been marketed and therefore the question of infringement must focus on what the ANDA applicant will likely market if its application is approved, an act that has not yet occurred."). While a section 271(e)(2) induced infringement claim may be speculative, it is not sufficiently so to contravene the case or controversy requirement. In *Glaxo*, we stated that section "271(e)(2) provided patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity." *Glaxo*, 110 F.3d at 1569, 42 USPQ2d at 1263. Additionally, in the setting of a declaratory judgment action, we have held that Article III does not preclude an action by a potential defendant for a determination that its conduct does not induce infringement, prior to any acts of infringement having taken place. *See Fina Research, S.A. v. Baroid Ltd.*, 141 F.3d 1479, 1485, 46 USPQ2d 1461, 1467 (Fed.Cir.1998) ("[W]e decline . . . to create a per se rule that an actual controversy predicated only on induced infringement may exist only if direct infringement has already occurred."). Thus, under *Fina*, a method of use patent holder could potentially bring an action against a generic drug manufacturer for induced infringement under 35 U.S.C. § 271(b) on the day the ANDA was approved before a single prescription of the generic drug was written by third party physicians. *Id.* A claim of induced infringement under section 271(e)(2), filed prior to the occurrence of direct infringement, does not violate the case or controversy requirement of Article III.

Summary judgment of non-infringement under section 271(e)(2), therefore, is inappropriate where the plaintiff can demonstrate the existence of a genuine issue of material fact with respect to the claim that the ANDA filer will induce infringement of its patent upon approval of the ANDA. *Warner-Lambert*, 316 F.3d at 1356, 65 USPQ2d at 1485. The district court found that Allergan presented a triable issue of

fact with respect to induced infringement by Alcon sufficient to allow the parties to proceed to discovery. *See supra* note 5; *Allergan*, 200 F.Supp.2d at 1225, 63 USPQ2d at 1431. Allergan presented evidence that third-party doctors and patients will likely infringe its two method of use patents and that Alcon and B & L may knowingly induce this infringement through their actions. *See Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553, 16 USPQ2d 1587, 1594 (Fed.Cir.1990) ("The plaintiff has the burden of showing that the alleged infringer's actions induced infringing acts *and* that he knew or should have known his actions would induce actual infringements.") (emphasis in original).

We must now determine whether Congress has prohibited the particular action for induced infringement brought by Allergan.

B. *Allergan's Action for Induced Infringement*

The district court concluded that, in the case of a method of use patent, section 271(e)(2) only makes the filing of an ANDA an act of infringement when the patent at issue claims the use for which FDA approval is sought in the ANDA. *Allergan*, 200 F.Supp.2d at 1230, 63 USPQ2d at 1435. Allergan argues that the district court erred in its ruling. For their part, Alcon and B & L contend that the district court correctly held that only when the ANDA speaks to the use that is claimed in the patent at issue may the patent holder bring suit under section 271(e)(2).

This issue was decided in *Warner-Lambert*. *Warner-Lambert* held that, pursuant to section 271(e)(2), a method of use patent holder may not sue an ANDA applicant for induced infringement of its patent, if the ANDA applicant is not seeking FDA approval for the use claimed in the patent and if the use claimed in the patent is not FDA-approved. *Warner-Lambert*, 316 F.3d at 1354-55, 65 USPQ2d at 1484. *Warner-Lambert* reasoned that "because an ANDA may not

seek approval for an unapproved or off-label use of a drug under 21 U.S.C. § 355(j)(2)(A)(i), it necessarily follows that 35 U.S.C. 271(e)(2)(A) does not apply to a use patent claiming only such a use." *Id.* at 1356, 65 USPQ2d at 1485.

In the *Warner-Lambert* case, Warner-Lambert obtained FDA approval through a NDA to market 1-aminomethyl-1-cyclohexane acetic acid ("gabapentin") for use in "adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy." This method of use was claimed in United States Patent No. 4,087,544 (the "epilepsy method patent"). Warner-Lambert is also the assignee of a second method of use patent, United States Patent No. 5,084,479 (the "neurodegenerative method patent"), which covers the treatment of neurodegenerative diseases with gabapentin.[7] Warner-Lambert claimed gabapentin itself in United States Patent No. 4,024,175 (the "product patent").

On April 17, 1998, Apotex filed an ANDA seeking approval to market a generic formulation of gabapentin upon the expiration of Warner-Lambert's epilepsy method patent on January 16, 2000. After Apotex notified Warner-Lambert that it had filed the ANDA and a Paragraph IV certification, Warner-Lambert instituted suit within 45 days in the United States District Court for the Northern District of Illinois. Warner-Lambert alleged that Apotex's submission of an ANDA for gabapentin was an act of infringement of its neurodegenerative method patent under 35 U.S.C. § 271 (e)(2).[8] The district court held that Warner-Lambert was entitled to proceed on an induced infringement theory under 35 U.S.C. § 271(e)(2) and that it was irrelevant whether

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[7] Epilepsy is not a neurodegenerative disease; therefore, the neurodegenerative method patent does not implicate the use of gabapentin for epilepsy.

[8] The gabapentin patent expired prior to Warner-Lambert's suit.

the asserted method of use patent claimed the use covered by Apotex's ANDA. The court concluded that "[t]he proper inquiry for this Court on the present motion is whether there exists a genuine issue of any material fact as to whether Apotex's gabapentin product, if manufactured, used, or sold, would actively induce the infringement of the '479 patent." *Warner-Lambert Co. v. Apotex Corp.*, 1999 WL 259946, at *3, 1999 U.S. Dist. LEXIS 6208, *10 (N.D.Ill. Apr. 8, 1999). After discovery, the district court entertained motions for summary judgment and concluded that there was no evidence that Apotex actively induced physicians to prescribe its product for neurodegenerative diseases or that Apotex knew its product would be prescribed for neurodegenerative diseases. *Warner-Lambert Co. v. Apotex Corp.*, 2001 WL 1104618, at *3, 2001 U.S. Dist. LEXIS 14592, *8 (N.D.Ill. Sept. 14, 2001). The district court therefore granted Apotex's motion for summary judgment of non-infringement. *Id.* at *4, 2001 U.S. Dist. LEXIS 14592, at *14. Warner-Lambert's appeal to this court followed.

On appeal, the *Warner-Lambert* court expressed concern that permitting a cause of action under section 271(e)(2) for off-label method of use patents would "confer substantial additional rights on pioneer drug patent owners that Congress quite clearly did not intend to confer." *Warner-Lambert*, 316 F.3d at 1359, 65 USPQ2d at 1487. The court also expressed concern about the threat of abuse by a patent holder attempting to extend its patent exclusion. *Id.* Accordingly, the court held that a method of use patent holder may not bring an action under section 271(e)(2) for infringement of a method of use patent that does not claim a FDA-approved use.

The court also determined that "Warner-Lambert would have needed to demonstrate the existence of a genuine issue of material fact to support a traditional infringement claim, *i.e.*, that Apotex induced or will induce infringement of the

neurodegenerative method patent." *Id.* at 1356, 65 USPQ2d at 1485. Upon considering Warner-Lambert's cause of action under section 271(b), the court concluded that "[i]n the absence of any evidence that Apotex has or will promote or encourage doctors to infringe the neurodegenerative method patent, there has been raised no genuine issue of material fact." *Id.* at 1364, 65 USPQ2d at 1491. The court, therefore, affirmed the district court's dismissal of Warner-Lambert's suit.

Under *Warner-Lambert*, Allergan is precluded from suing Alcon and B & L under section 271(e)(2) for inducing infringement of the '415 and '741 patents, because Alcon and B & L are not seeking FDA approval for the uses claimed in the patents and because the uses claimed in the patents are not FDA- approved.[9]

CONCLUSION

For the foregoing reasons, the decision of the district court granting summary judgment in favor of Alcon and B & L is affirmed.

COSTS

Each party shall bear its own costs.

AFFIRMED.

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[9] Allergan's alternative argument is that section 271(e)(2) provides a direct cause of action that makes an ANDA filer in a case such as this liable for infringement based simply upon the filing of the ANDA. According to Allergan, "[o]n its face, § 271(e)(2)(A) requires that, if a person submits an ANDA for a drug, the use of which is claimed in a patent, in order to engage in the commercial manufacture, use, or sale of the drug, that person has committed an act of infringement." *Warner-Lambert* bars Allergan's direct infringement claim. In any event, *Glaxo* makes it clear that section 271(e)(2) requires proof of all the elements of infringement. *Glaxo*, 110 F.3d at 1567, 42 USPQ2d at 1262 ("The plain language of the statute does not alter a patentee's burden of proving infringement . . . ."). We reject Allergan's contention that section 271(e)(2) acts as a strict liability statute.

SCHALL, Circuit Judge, concurring in the judgment, with whom Circuit Judge CLEVENGER joins.

Because this case is controlled by *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 65 USPQ2d 1481 (Fed. Cir.2003), we must affirm the district court's grant of summary judgment in favor of Alcon and B & L, and I therefore join in the judgment of the court in this case. However, I write separately to express my respectful disagreement with the decision of the court in *Warner-Lambert*.[1] In my view, contrary to the conclusion reached in *Warner-Lambert*, a claim of induced infringement like the one asserted by Allergan against Alcon and B & L is cognizable under 35 U.S.C. § 271(e)(2). I say this for the following reasons:

A. *35 U.S.C. § 271(e)(2)*

Statutory interpretation necessarily begins with the text of the statute. *Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 438, 119 S.Ct. 755, 142 L.Ed.2d 881 (1999) ("As in any case of statutory construction, our analysis begins with the language of the statute.") (quotations omitted). Our task is to determine whether the statutory language "has a plain and unambiguous meaning with regard to the particular dispute in the case. Our inquiry must cease if the statutory language is unambiguous and 'the statutory scheme is coherent and consistent.'" *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340, 117 S.Ct. 843, 136 L.Ed.2d 808 (1997) (quoting *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 240, 109 S.Ct. 1026,

[1] Both *Warner-Lambert* and this case were argued and submitted for decision the week of October 7, 2002. When *Warner-Lambert* and this case were argued, the issues they presented were ones of first impression.

103 L.Ed.2d 290 (1989)). I believe the language of 35 U.S.C. § 271(e)(2) is "plain and unambiguous." The statute provides in relevant part as follows:

> (2) It shall be an act of infringement to submit—
>
> (A) an [ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . .
>
> if the purpose of such submission is to obtain approval under [the FDCA] to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2) (emphasis added).

In interpreting a statute, we presume that Congress intended to give words their ordinary meanings. *Asgrow Seed Co. v. Winterboer*, 513 U.S. 179, 187, 115 S.Ct. 788, 130 L.Ed.2d 682, 33 USPQ2d 1430, 1433 (1995). In section 271(e)(2), Congress chose to employ the clause "the use of which is claimed in a patent" in two places. In both places, the words "of which" refer to the word "drug." Thus, Congress did not tie "the use" to the uses stated in the ANDA. Rather, Congress tied "the use" to the uses claimed in the patent. In short, the plain language of section 271(e)(2) compels the conclusion that an action for infringement may lie based upon the filing of an ANDA for a drug whose use is patented, even if approval for the patented use is not sought in the ANDA. 35 U.S.C. § 271(e)(2). Alcon's and B & L's conduct brings them squarely within the language of section 271(e)(2). That is because each has filed an ANDA seeking approval for the commercial sale of a drug (brimonidine) whose use is claimed in two patents that have not yet expired, the '415 patent and the '741 patent.

Alcon argues that an action for infringement of a method of use patent may only be brought under 35 U.S.C. § 271(e)(2)

in the case of a "controlling use patent."[2] Congress was fully aware of the concept of controlling use. See H.R.Rep. No. 98-857, pt. 1, at 22, reprinted in 1984 U.S.C.C.A.N. 2647, 2655. Yet, Congress declined to employ that concept when it wrote section 271(e)(2). *Chicago v. Envtl. Def. Fund*, 511 U.S. 328, 337, 114 S.Ct. 1588, 128 L.Ed.2d 302 (1994) ("But it is the statute, and not the Committee Report, which is the authoritative expression of the law, and the statute prominently *omits* reference to generation.") (emphasis in original).

In order to prevail on a claim of infringement under section 271(e)(2), a patent holder must establish that "if the drug were approved based upon the ANDA, the manufacture, use, or sale of that drug would infringe the patent in the conventional sense." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569, 42 USPQ2d 1257, 1263 (Fed.Cir.1997). That is because section 271(e)(2) "makes it possible for a patent owner to have the court determine whether, if a particular drug were put on the market, it would infringe the relevant patent." *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1135, 36 USPQ2d 1641, 1642-43 (Fed.Cir.1995). Consequently, it has been said that when an ANDA filer makes a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii), the patent holder can establish infringement if it shows that the certification "is in error as to whether commercial manufacture, use, or sale of the new drug (none of which has actually occurred) violates the relevant patent." *Eli Lilly Co. v. Medtronic, Inc.*, 496 U.S. 661, 678, 110 S.Ct. 2683, 110 L.Ed.2d 605, 15 USPQ2d 1121, 1130 (1990). Thus, in order to prevail on a claim of induced infringement under section 271(e)(2), a patent holder must establish the traditional elements of a claim of induced infringement. In other words, the patentee must show that, if

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[2] As explained below, a "controlling use patent" is a patent that claims an indication for a drug for which an ANDA applicant is seeking FDA approval.

the ANDA is approved, the accused infringer will induce a third party to directly infringe the asserted patent and that the accused infringer knows or should know that his actions will induce infringement. *See Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553, 16 USPQ2d 1587, 1594 (Fed.Cir.1990).

Absent *Warner-Lambert*, I would hold that Allergan's claims of induced infringement against Alcon and B & L are cognizable under 35 U.S.C. § 271(e)(2). In that regard, I note what I believe to be the difference between (1) an infringement action involving a method of use patent that claims a use that is the subject of an ANDA and (2) an infringement action involving a patent that claims a use that is not the subject of an ANDA. The only difference between the two types of actions is the degree of proof required. In each case, in order to establish infringement under section 271(e)(2), a patent holder must prove that, upon approval of the ANDA, the ANDA filer will actively induce a third party to directly infringe the asserted patent.[3] *Id.* In the first case, the ANDA filer included a request to use the patented method of use in the ANDA itself. The request in the ANDA is highly probative evidence of likely induced infringement. The ANDA request, however, is just that, evidence. In the second case, a patent holder is not precluded from producing other evidence that also shows induced infringement. As we stated in *Glaxo*, "[t]he plain language of the statute does not . . . mandate an infringement analysis limited to the scope of the approval sought." *Glaxo*, 110 F.3d at 1567, 42 USPQ2d at 1262.

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[3] A patentee could only allege direct infringement of a method of use patent if the ANDA applicant experimented with or otherwise employed the method of use claimed in the patent and was not protected from infringement by the experimental use exemption granted by the Hatch-Waxman Act. *See* 35 U.S.C. § 271(e)(1).

Under my reading of the statute, Allergan has stated a cause of action for induced infringement under section 271(e)(2) and would have been able to use evidence outside the ANDA itself to show infringement of its patents. It alleges that the '415 and '741 patents will be infringed by doctors who will prescribe Alcon's and B & L's generic brimonidine products for neuroprotection. It also alleges that, with knowledge of the '415 and '741 patents, Alcon and B & L have taken steps to promote brimonidine for neuroprotection. In short, Allergan has asserted a viable claim of induced infringement under 35 U.S.C. § 271(b). The same cannot be said of Warner-Lambert's claim. Even under my reading of the statute, Warner-Lambert's case would have been dismissed and the FDA permitted to approve applicant Apotex's ANDA. Warner-Lambert was not able to present evidence tending to show that Apotex had encouraged, or would encourage, doctors to infringe Warner-Lambert's neurodegenerative method patent.[4]

In my view, Allergan's case is one in which section 271(e)(2) would benefit both the ANDA applicant and the patentee. The ANDA applicant would benefit by challenging the scope of a patentee's rights before the patent expires and before the applicant has invested in production and manufacturing facilities in reliance on its approved ANDA. The patentee, in turn, would profit by enforcing its patent rights before a generic drug manufacturer has moved into the market as a competitor. This balance is what Congress intended when it created the artificial act of infringement

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[4] The *Warner-Lambert* court stated that "[i]n the absence of any evidence that Apotex has or will promote or encourage doctors to infringe the neurodegenerative method patent, there has been raised no genuine issue of material fact" under section 271(b). *Warner-Lambert*, 316 F.3d at 1364, 65 USPQ2d at 1491.

under section 271(e)(2).[5] In the absence of the section 271(e)(2) mechanism, the owner of a method of use patent claiming an off-label use will bring a section 271(b) induced infringement action, after the ANDA has been approved by the FDA, to enjoin infringement of its patent.

Alcon and B & L point to the fact that an ANDA may not seek approval from the FDA for an unapproved use of a drug.[6] Based upon that fact, they argue that they are precluded by threat of civil and criminal penalties from applying to the FDA to market their generic versions of brimonidine for an unapproved use, such as neuroprotection. I am not persuaded by this argument. The fact that an ANDA may not seek approval from the FDA for an unapproved use of a drug does not mean that section 271(e)(2) fails to create an act of infringement with respect to a patent that claims that unapproved use. It merely suggests that a responsible drug manufacturer will be deterred from marketing a drug for an unapproved use in violation of the law. The threat of a patent infringement suit would further deter a generic drug manufacturer from marketing a generic drug for an off-label patented use and would provide a patentee an enforcement mechanism in the event a generic drug manufacturer violates the law. As I have explained, I believe that section 271(e)(2),

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[5] These cases do not present a significant threat of abuse by a patent holder attempting to extend its patent exclusion through extensive litigation, because Congress gave district courts the ability to end a party's attempts to delay litigation by controlling the timing of the suit. *See* 21 U.S.C. § 355(j)(5)(B)(iii) (granting the court discretion to change the date on which an ANDA may be approved if "either party to the action failed to reasonably cooperate in expediting the action").

[6] *See* 21 U.S.C. § 355(j)(2)(A)(i) (An ANDA must contain information "to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) . . ."); 21 U.S.C. § 331(d) (prohibited conduct); 21 U.S.C. § 332(a) (injunctions); 21 U.S.C. § 333(a) (criminal penalties); 21 U.S.C. § 334(a)(1) (seizure of the drug).

by its terms, gives a method of use patent owner the right to bring an action for induced infringement based upon a generic drug manufacturer's filing of an ANDA even if the ANDA does not refer to the use claimed in the patent.

B. *21 U.S.C. § 355(b)(1), 21 U.S.C. § 355(j)(2)(A), and 35 U.S.C. § 271(e)(4)*

Alcon and B & L point to (i) 21 U.S.C. § 355(b)(1) (the "Patent Listing Provision"); (ii) 21 U.S.C. § 355(j)(2)(A) (the "Patent Certification Provision"); and (iii) 35 U.S.C. § 271(e)(4) (the "Remedy Provision"). They argue that a correct reading of these statutes undermines the proposition that a method of use patent holder may bring an action under 35 U.S.C. § 271(e)(2) for induced infringement when the patent at issue claims a use for a drug not approved by the FDA and the claimed use is not the use of the drug for which the ANDA filer seeks FDA approval. *See Kokoszka v. Belford*, 417 U.S. 642, 650, 94 S.Ct. 2431, 41 L.Ed.2d 374 (1974) ("When 'interpreting a statute, the court will not look merely to a particular clause in which general words may be used, but will take in connection with it the whole statute . . . and the objects and policy of the law . . . and give to it such a construction as will carry into execution the will of the Legislature . . . .'") (quoting *Brown v. Duchesne*, 19 How. 183, 194, 15 L.Ed. 595 (1857)). I address these contentions in turn.

(i) *The Patent Listing Provision, 21 U.S.C. § 355(b)(1)*

The Patent Listing Provision provides in pertinent part as follows:

> The applicant shall file with the [NDA] the patent number and expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed

> by the owner engaged in the manufacture, use, or sale of the drug.

21 U.S.C. § 355(b)(1) (emphasis added).[7] Alcon and B & L assert that, as far as method of use patents are concerned, a NDA applicant may only file the patent number and expiration date ("patent information") for patents that claim uses that are stated in the NDA. They also argue that a successful NDA applicant must seek to have removed from the Orange Book any patent that does not claim a use for which the NDA is approved.[8] Accordingly, Alcon and B & L contend that Allergan, as the NDA holder for brimonidine, improperly obtained the listing of its method of use patents in the Orange Book because the neuroprotective function of brimonidine is not an indication for brimonidine that has been approved by the FDA. Allergan responds that the Patent Listing Provision does not limit the method of use patents that should be listed in the Orange Book to only those method of use patents that cover uses approved through the NDA process.

In my view, Allergan's reading of the statute is true to its words. First, Congress chose to include the word "any" before "patent." Congress thus required that "*any* patent . . . which claims a method of using such drug . . ." must be listed. 21 U.S.C. § 355(b)(1) (emphasis added). Second, in the part of the statute that states "[t]he applicant shall file with the [NDA] the patent number and the expiration date of any patent which claims the drug for which the applicant

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[7] The holder of an approved NDA is required to provide the patent number and expiration date of similar method of use patents that are issued after the date the NDA is approved. *See* 21 U.S.C. § 355(c)(2).

[8] This court has held that "a generic drug manufacturer cannot bring a declaratory judgment action or an injunctive action against a NDA holder under either the [FDCA] or the patent laws requiring it to take steps to 'delist' a patent from the Orange Book." *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1373-74, 61 USPQ2d 1414, 1417 (Fed.Cir.2002).

submitted the application," the word "drug" is followed by the words "for which the applicant submitted the application." *Id.* However, the "or which claims a method of using" language of the statute, which immediately follows, contains no limitation that the method of using the drug be contained in the NDA. I believe the meaning of the statutory language is plain and unambiguous. A pharmaceutical manufacturer, such as Allergan, who holds an approved NDA for a drug is required to provide patent information for listing in the Orange Book for any patent which claims a method of using the approved drug that is issued after the NDA is approved.

It is a concept of general patent law under 35 U.S.C. § 271(b) that the owner of a method of use patent may assert a claim of induced infringement if a third party, not licensed by the owner of the patent, engages in the patented use due to the active inducement of a product manufacturer. *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus.*, 145 F.3d 1303, 1311, 46 USPQ2d 1752, 1759 (advertisements to customers encouraging infringing use were sufficient to support claim of induced infringement). This concept supports the general purpose of the Patent Listing Provision, which is to give notice to a potential infringer (direct or induced) of patents upon which the patentee could reasonably bring a suit. Moreover, in *Eli Lilly*, the Supreme Court described the Patent Listing Provision requirement as follows: "Pioneer drug applicants are required to file with the FDA the number and expiration date of any patent which claims . . . a method of using such drug." *Eli Lilly*, 496 U.S. at 677, 110 S.Ct. 2683, 15 USPQ2d at 1129 (emphasis added). The Court described the statute in terms that did not limit its application to only those patented methods of using the drug that are approved by the FDA. *Id.*

Alcon also points to the FDA regulation that implements the Patent Listing Provision, 21 C.F.R. § 314.53(b).[9] Specifically, Alcon relies on the part of the regulation that states: "For patents that claim a method of use, the applicant shall submit information only on those patents that claim indications or other conditions of use of a pending or approved application." 21 C.F.R. § 314.53(b) (emphasis added). Alcon argues that this means that only method of use patents claiming uses that have been approved by the FDA may be submitted for listing in the Orange Book. Allergan, on the other hand, reads section 314.53(b) as requiring the listing of patents, such as the '415 patent and the '741 patent, that claim "other conditions of use," such as a neuroprotective use for brimonidine, for a drug that is the subject of a NDA or an approved NDA. In short, Allergan urges that section 314.53(b) does not limit the broad language of 21 U.S.C. § 355(b)(1). I agree.

I note at the outset that Alcon's reading of the regulation is inconsistent with the clear language of 21 U.S.C. § 355(b)(1), which I have just examined. *See Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 484, 121 S.Ct. 903, 149 L.Ed.2d 1 (2001) (rejecting an agency's interpretation of a statutory requirement because the interpretation was at odds with the "structure and manifest purpose" of the statute). A court is properly reluctant to embrace a reading of a regulation that makes the regulation conflict with the statute that it is meant to implement. *See Gomez v. Dept. of Air Force*, 869 F.2d 852, 858 (5th Cir.1989) ("[W]e are compelled to interpret the regulation in accordance with Title VII because it is the governing statute.").

As I read section 314.53(b), Allergan was required to provide information for the Orange Book for any method of

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[9] All references are to regulations as set forth in the 2002 version of the Code of Federal Regulations.

use patents it held that claimed "indications or other conditions of use of a pending or approved application." The '415 and '741 patents were covered by the language of the regulation because they claimed "other conditions of use" (the use of brimonidine for neuroprotection) of a "pending or approved application" (Allergan's approved NDA application for brimonidine).[10] In short, I see nothing in the Patent Listing Provision that supports the argument that Allergan is barred from asserting its claim of induced infringement against Alcon and B & L.[11]

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[10] The regulation that governs the content and format of NDAs is set forth at 21 C.F.R. § 314.50. The regulation indicates that the FDA distinguishes between a drug product's proposed indications of use and other uses of the drug product. *Compare* 21 C.F.R. § 314.50(a)(1) (requiring submission of the drug product's "proposed indications for use") with 21 C.F.R. § 314.50(d)(5)(iv) (requiring submission of "relevant" clinical data concerning "uses of the drug other than those proposed in the application").

[11] On October 24, 2002, the FDA issue a proposed rule that would, among other things, amend 21 C.F.R. § 314.53(b). *See* Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not be Infringed, 67 Fed.Reg. 65,448 (proposed October 24, 2002). Under the proposed rule, the part of section 314.53(b) that speaks to method of use patents would be amended to read as follows:

> For patents that claim a method of use, the [NDA] applicant shall submit information only on those patents that claim indications or other conditions of use that are the subject of a pending or approved application.

67 Fed.Reg. at 65,451 (emphasis added).

Alcon and B & L argue that the FDA's proposed rule supports their contention that so-called "off-label" use patents—patents such as the '415 and '741 patents that claim unapproved uses of a drug—"were not intended to serve as the basis for an action under 35 U.S.C. § 271(e)(2)." Allergan responds that the "perceived need of FDA to change its current regulation indicates that the current regulation permits the listing of all

(ii) *The Patent Certification Provision, 21 U.S.C. § 355(j)(2)(A)*

The Patent Certification Provision provides in pertinent part as follows:

> An [ANDA] shall contain—
>
> (i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");
>
> * * *
>
> (vii) a certification . . . with respect to each patent which claims the listed drug . . . or which claims a *use* for such *listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section*—
>
> (I) that such patent information has not been filed,
>
> (II) that such patent has expired,
>
> (III) of the date on which such patent will expire, or

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method of use patents concerning an approved drug whether or not the use is approved."

I am reluctant to look to a notice of proposed rule making as a tool of statutory construction. *See Commodity Futures Trading Comm'n v. Schor,* 478 U.S. 833, 845, 106 S.Ct. 3245, 92 L.Ed.2d 675 (1986) ("It goes without saying that a proposed regulation does not represent an agency's considered interpretation of its statute and that an agency is entitled to consider alternative interpretations before settling on the view it considers most sound."). In any event, having concluded that under the plain language of 21 U.S.C. § 355(b)(1), Allergan was required to provide patent information for the '415 patent and '741 patent when the patents issued, I would not construe the language of the proposed amended version of section 314.53(b). *See Whitman,* 531 U.S. at 484, 121 S.Ct. 903; *Gomez,* 869 F.2d at 858.

> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and
>
> (viii) if with respect to the listed drug referred to in clause (i) information was filed under [the Patent Listing Provision] for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

21 U.S.C. § 355(j)(2)(A) (emphasis added).

Alcon and B & L contend that the words "for which the applicant is seeking approval under this subsection" in clause (vii) refer to the term "use," not "listed drug." Therefore, they argue, an ANDA filer is not required to make a Paragraph IV certification with respect to a method of use patent that does not claim a use for which the ANDA filer is seeking FDA approval. Alcon and B & L reason that this demonstrates that section 271(e)(2) was not meant to support a claim of induced infringement such as the one advanced by Allergan. Allergan argues the contrary, stating that the phrase at issue modifies "listed drug," not "use."

As a matter of statutory interpretation, I believe Allergan is correct. There are two parallel "for which" clauses in the Patent Certification Provision: "for which the applicant is seeking approval under this subsection" and "for which information is required to be filed under subsection (b) or (c) of this section." The references in the second clause to "subsections (b) and (c) of this section" are to 21 U.S.C. § 355(b) and 21 U.S.C. § 355(c), respectively. As already discussed, these subsections require the NDA filer or the holder of an approved NDA to submit for listing in the Orange Book specified information with respect to the drug, including "any patent which claims . . . a method of using [the drug covered by the NDA] and with respect to which a claim of patent infringement could reasonably be asserted if a person not

licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. §§ 355(b)(1) and 355(c)(2). The second clause, therefore, must modify "listed drug." Since the first "for which" clause is parallel to the second, it must also modify "listed drug." Moreover, the first clause is subject to the restriction "under this subsection." 21 U.S.C. § 355(j)(2)(A)(vii). Subsection 355(j) deals with the filing of ANDAs for new drugs, stating that "[a]ny person may file with the Secretary an abbreviated application for the approval of a new drug." 21 U.S.C. § 355(j)(1). In my view, this supports the parallel construction of the sentence and confirms that the phrase disputed by Allergan and Alcon modifies the term "listed drug," as Allergan suggests. Therefore, I conclude that the Patent Certification Provision does not alter the plain meaning of 35 U.S.C. § 271(e)(2).

Alcon and B & L cite the legislative history of the Hatch-Waxman Act concerning the Patent Certification Provision for the proposition that an ANDA applicant need not make a Paragraph IV certification with respect to a patent that claims a method of using a drug for which the ANDA does not seek approval. The legislative history states in relevant part as follows:

> . . . [A]n ANDA must include a certification by the applicant regarding the status of certain patents applicable to the listed drug if the patent information has been submitted under section 505(b) or (c). With respect to all product patents which claim the listed drug and all use patents which claim an indication for the drug for which the applicant is seeking approval (hereinafter described as a *controlling use patent*), the applicant must certify, in his opinion and to the best of his knowledge, as to one of four circumstances.
>
> * * *
>
> If appropriate, the applicant may certify that one or more of the product or *controlling use patents* provided have expired . . . . [A]n applicant may certify if applicable

> that one or more of the product or *controlling use patents* are invalid or will not be infringed.
>
> The committee recognizes that in some instances an applicant will have to make multiple certifications with respect to product or *controlling use patents.* For example, if the product patent has expired and a valid *controlling use patent* will not expire for three years, then the applicant must certify that one patent has expired and the other will expire in three years. The committee intends that the applicant make the appropriate certification for each product and *controlling use patent.*

H.R.Rep. No. 98-857, pt. 1, at 22, reprinted in 1984 U.S.C.C.A.N. 2647, 2655 (emphasis added).

Alcon and B & L urge that the material quoted from the House Report demonstrates that a claim of infringement under 35 U.S.C. § 271(e)(2) may, in the case of a method of use patent, only be brought if the ANDA filer seeks approval for the use claimed in the patent. I do not agree. The legislative history states that "controlling use patents" include "all use patents which claim an indication for the drug for which the applicant is seeking approval," while section 355(j)(2)(A) requires "a certification . . . with respect to each patent . . . which claims a use for such listed drug for which the applicant is seeking approval." The language that must be interpreted in the statute is virtually the same as the language that appears in the House Report. Under these circumstances, one might say that the legislative history, in fact, is no narrower than section 355(j)(2)(A) and can be interpreted consistently.

In any event, Alcon's and B & L's reading of the phrase "controlling use patent" leads to an interpretation of the Patent Certification Provision that is inconsistent with what I have just concluded is the plain meaning of the statute. Given its near symmetry with the language of the statute, I do not believe the statement from the House Report upon which

Alcon and B & L rely is sufficient to overcome this plain meaning, and therefore, alter the Patent Certification Provision requirement. *Garcia v. United States*, 469 U.S. 70, 75, 105 S.Ct. 479, 83 L.Ed.2d 472 (1984) ("[O]nly the most extraordinary showing of contrary intentions from [the legislative history] would justify a limitation on the "plain meaning" of the statutory language."). I conclude that the legislative history relating to the Patent Certification Provision does not assist Alcon and B & L in their interpretation of section 271(e)(2).

Additionally, the Patent Listing Provision, discussed in section (B)(i) *supra*, requires a NDA holder to submit to the FDA for listing in the Orange Book all patents that claim a method of using the approved drug "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). In my view, a distorted interpretation of the Patent Certification Provision results if one does not interpret 21 U.S.C. § 355(j)(2)(A) to require an ANDA filer to make a Paragraph IV certification for a method of use patent listed in the Orange Book with respect to which a claim of patent infringement could reasonably be asserted against the filer, even if the filer did not seek approval for the patented use in the ANDA. This is especially true because many patentees look to the Paragraph IV certification for error when establishing a claim of infringement under 35 U.S.C. § 271(e)(2). *See Eli Lilly*, 496 U.S. at 678, 110 S.Ct. 2683, 110 L.Ed.2d 605, 15 USPQ2d at 1130. Accordingly, I believe that an ANDA applicant must make a Paragraph IV certification for each listed patent that claims the drug included in the ANDA and for each listed method of use patent related to that drug that could form the basis for a claim of infringement.[12]

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[12] If a patent is not listed in the Orange Book, a Paragraph I certification may be appropriate.

I agree with Alcon and B & L that Congress intended a generic drug manufacturer to be able to gain approval from the FDA to manufacture and market an unpatented drug for a use that is not covered by a patent. Both 21 U.S.C. § 355(j)(2)(A)(viii) and the example in House Report 98-857 suggest that this is the case. Section 355(j)(2)(A)(viii) requires an ANDA filer to state that it is not applying for the patented use. The example in the House Report illustrates this concept and states as follows: "For example, the listed drug may be approved for two indications. If the applicant is seeking approval only for indication No. 1, and not indication No. 2 because it is protected by a use patent, then the applicant must make the appropriate certification and a statement explaining that it is not seeking approval for indication No. 2." H.R. Rep. No. 98-857, pt. 1, at 22-23 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647-48. However, I do not share the conclusion that Alcon and B & L draw from the language of section 355(j)(2)(A)(viii) and from the example in the House Report; namely that Congress intended a patent holder to be without recourse when a generic drug manufacturer will induce a third party to infringe a method of use patent upon approval of an ANDA. I believe the conclusion is at odds with the plain language of 35 U.S.C. § 271(e)(2). In addition, as the Supreme Court stated in *Eli Lilly*, "[the ANDA] scheme will not work, of course, if the holder of the patent pertaining to the pioneer drug is disabled from establishing in court that there has been an act of infringement." *Eli Lilly*, 496 U.S. at 678, 110 S.Ct. 2683, 110 L.Ed.2d 605, 15 USPQ2d at 1130.

(iii) *The Remedy Provision, 35 U.S.C. § 271(e)(4)*

Finally, Alcon and B & L argue that the exclusive remedies of 35 U.S.C. § 271(e)(4) are particularly severe in a case where an ANDA filer is seeking approval for the production of an unpatented drug for an unpatented use. From that point, they contend that Congress could only have meant those

remedies to apply in the case of a method of use patent that claims an approved use of a drug for which the ANDA filer seeks approval, and that, therefore, the reach of section 271(e)(2) must be limited to such patents. The Remedy Provision of section 271(e)(4) states in relevant part as follows:

> (4) For an act of infringement described in paragraph (2)—
>
> (A) the court shall order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,
>
> (B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug . . ., and
>
> (C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug. . . .
>
> The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2). . . .

35 U.S.C. § 271(e)(4). I do not think that Alcon's and B & L's argument that the remedies provided in section 271(e)(4) are extreme in the situation where there is a determination of induced infringement under 35 U.S.C. § 271(e)(2) is sufficient to override the plain language of the statute. It is within the purview of Congress to fashion remedies in the manner it deems appropriate. The Remedy Provision does not require that section 271(e)(2) be limited to

method of use patents that claim an approved use of a drug for which the ANDA filer seeks approval.

I do note, however, that Alcon's and B & L's arguments concerning the Remedy Provision bring into focus the fact that, to a large extent, their contentions in this case are grounded in policy considerations. It is the view of Alcon and B & L and the holding of *Warner-Lambert* that a method of use patent holder, such as Allergan, should not be able to bring an action for induced infringement under 35 U.S.C. § 271(e)(2) against a generic drug manufacturer who submits an ANDA seeking approval to market a drug for an approved, non-patented use that is different from the unapproved use for the same drug that is claimed in the method of use patent. I conclude, however, that the language of section 271(e)(2) and the overall statutory scheme of the Hatch-Waxman Act do not bar such an action.

If Congress determines that the owner of a method of use patent should not have an action for induced infringement against an ANDA filer in the circumstances that exist in this case, or that a more lenient injunctive remedy should be available for infringers of such method of use patents, it can amend section 271(e)(2) or section 271(e)(4) so as to compel a result different from the one I would reach. *See Reid v. Dep't of Commerce*, 793 F.2d 277, 284 (Fed.Cir.1986) ("'The remedy for any dissatisfaction with the results in particular cases lies with Congress' and not with this court. 'Congress may amend the statute; we may not.'") (quoting *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 576, 102 S.Ct. 3245, 73 L.Ed.2d 973 (1982)). However, until Congress takes such action, I believe we must apply the statute as written.

For the foregoing reasons, I respectfully disagree with the decision of the court in *Warner-Lambert*. I would hold that 35 U.S.C. § 271(e)(2) may serve as the basis for an infringement action with respect to a method of use patent for an off-

label use, when the patentee can prove that an ANDA applicant applying for the right to manufacture, use, or sell a drug actively encourages doctors and/or patients to use the generic version of the drug for the patented off-label use once the ANDA is approved. As a result, were I free to do so, I would reverse the decision of the district court and would remand the case in order to allow Allergan's suit for induced infringement under section 271(e)(2) to proceed.[13]

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[13] As noted in the per curiam opinion, the district court found that, as far as Allergan's claim of induced infringement against Alcon was concerned, the record before the court was sufficient to present a triable issue of fact or, at the least, was sufficient to permit Allergan to conduct discovery under Fed.R.Civ.P. 56(f). In its motion for summary judgment, B & L argued that Allergan could raise no triable issue of fact regarding whether, if its ANDA were approved, B & L would induce infringement of the '415 and '741 patents. In granting Alcon's and B & L's motions for summary judgment, the district court did not address B & L's contention that Allergan could not establish a genuine issue of material fact with respect to B & L's alleged inducing of infringement. On remand, the district court would have the opportunity to consider this issue.

LINN, Circuit Judge, concurring in the judgment.

I concur in the conclusion of the panel that this case is controlled by *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed.Cir.2003). I also agree that it is reasonable, as a matter of patent policy, to conclude, as the *Warner-Lambert* panel did, that it should not be "an act of infringement to submit an ANDA for approval to market a drug for a use when neither the drug nor that use is covered by an existing patent, and the patent at issue is for a use not approved under the NDA." *Id.* at 1354-55. I write separately to express my disagreement not with the logical conclusions reached by the court in *Warner-Lambert* but with the court's looking beyond the congressional intent expressed in the plain meaning of the statute to reach those conclusions. In my opinion, the court in *Warner-Lambert* has ventured beyond our interpretive role and, in interpreting the complex statutory scheme before it, has allowed its policy choices and its evaluation of the legislative history—reasonable as they may be—to override the terms of the statute chosen by Congress.

While the statutory scheme forming the basis for an ANDA filing is hardly a model of clarity, *see Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 679, 110 S.Ct. 2683, 110 L.Ed.2d 605 (1990), 35 U.S.C. § 271(e)(2) is itself not grammatically complex. It simply states that "[i]t shall be an act of infringement to submit—(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act . . . for a drug claimed in a patent or the use of which is claimed in a patent." The normal reading of "the use" in this context is simply "any use." This is also consistent with the surrounding provisions of the Hatch-Waxman Act, as carefully described in Judge Schall's concurring opinion. There is no indication that Congress deliberately selected the definite article in order to restrict the scope of the term to a use already approved by the FDA. Rather, the language employed is simply the natural way to express the concept

that the filing of an ANDA to produce a drug having a patented use is an act of infringement. In such cases, our judicial role is to follow the plain meaning of the particular provision at issue, even if there are policy concerns that could be addressed by declining to adhere to the strict literal terms of the statutory language Congress has employed. *See Fed. Bureau of Investigation v. Abramson*, 456 U.S. 615, 633, 102 S.Ct. 2054, 72 L.Ed.2d 376 (1982) (O'Connor, J., dissenting) ("A judge must not rewrite a statute, neither to enlarge nor to contract it. Whatever temptations the statesmanship of policy-making might wisely suggest, construction must eschew interpolation and evisceration.") (*quoting* Felix Frankfurter, *Some Reflections on the Reading of Statutes*, 47 Colum. L.Rev. 527, 533 (1947)).

In effect, the court in *Warner-Lambert* reads the words "the use for which the FDA has granted an NDA" into the statute, concluding that "it is clear that the phrase 'the use' in § 271(e)(2)(A) refers to the use for which the FDA has granted an NDA." *Warner-Lambert*, 316 F.3d at 1356. Moreover, the opinion discusses the purposes of the Hatch-Waxman Act and concludes that a broader interpretation of section 271(e)(2) would lead to undesirable consequences:

> Warner-Lambert's proposed interpretation [that "the use" means "any use"] is inconsistent with both of the stated purposes of the Hatch-Waxman Act, and would confer substantial additional rights on pioneer drug patent owners that Congress quite clearly did not intend to confer. If Warner-Lambert's interpretation were correct, for example, an NDA holder would be able to maintain its exclusivity merely by regularly filing a new patent application claiming a narrow method of use not covered by its NDA. It would then be able to use § 271(e)(2)(A) as a sword against any competitor's ANDA seeking approval to market an off-patent drug for an approved use not covered by the patent. Generic

> manufacturers would effectively be barred altogether from entering the market.

Warner-Lambert, 316 F.3d at 1359. However compelling such arguments may be, it is the function of Congress, not the courts, to shape legislation in accordance with policy goals. "Under our constitutional framework, federal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy." *United States v. Rutherford*, 442 U.S. 544, 555, 99 S.Ct. 2470, 61 L.Ed.2d 68 (1979). *See also Artuz v. Bennett*, 531 U.S. 4, 10, 121 S.Ct. 361, 148 L.Ed.2d 213 (2000) ("Whatever merits these and other policy arguments may have, it is not the province of this Court to rewrite the statute to accommodate them."); *Badaracco v. Comm'r of Internal Revenue*, 464 U.S. 386, 398, 104 S.Ct. 756, 78 L.Ed.2d 549 (1984) ("Courts are not authorized to rewrite a statute because they might deem its effects susceptible of improvement."); *Bankamerica Corp. v. United States*, 462 U.S. 122, 140, 103 S.Ct. 2266, 76 L.Ed.2d 456 (1983) ("[W]e are not to rewrite the statute based on our notions of appropriate policy.").

It is for Congress, not this court, to explain why the intent expressed in the plain meaning of the language used in section 271(e)(2) does not reflect its intent as to the policy governing applications by generic drug manufacturers to produce drugs that may have patented "off-label" uses. *See Blount v. Rizzi*, 400 U.S. 410, 419, 91 S.Ct. 423, 27 L.Ed.2d 498 (1971) ("[I]t is for Congress, not this Court, to rewrite the statute."). The importance of this issue suggests that Congress consider revisiting the terms of the Hatch-Waxman Act to clarify or confirm its intent. In the absence of any congressional action to that end, I would interpret the statute as set forth in Judge Schall's concurring opinion if I were not bound to follow the precedent of our *Warner-Lambert* decision.

APPENDIX B

UNITED STATES DISTRICT COURT
C.D. CALIFORNIA

No. SA CV 02-40 DOC.

ALLERGAN, INC.; Allergan Sales, Inc.,
Plaintiffs,

v.

ALCON LABORATORIES, INC.; Alcon Research, Ltd.; Alcon Universal, Ltd.; Bausch & Lomb, Inc.,
Defendants.

May 8, 2002.

ORDER GRANTING ALCON DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

CARTER, District Judge.

Before the Court is Defendants' Alcon Laboratories, Inc., Alcon Research, Ltd., and Alcon Universal, Ltd.'s (collectively Alcon) motion for summary judgment on Plaintiffs' Allergan, Inc. and Allergan Sales, Inc.'s (collectively Allergan) complaint for patent infringement. After reviewing the moving, opposing, and replying papers, after oral argument on April 29, 2002, and for the reasons set forth below, the Court GRANTS Alcon's motion.

I.

BACKGROUND

A. Glaucoma

Open-angle glaucoma, the most common form of glaucoma, is a disease of the eye that leads to a gradual loss of

vision. Glaucoma is caused by damage to optical cells. As those cells are damaged, vision becomes impaired. Generally, individuals that suffer from glaucoma lose their peripheral vision and subsequently develop blind spots at the sides. If not arrested, it may lead to blindness. Risk factors for glaucoma have traditionally included people with diabetes, high blood pressure, near sightedness, a family history of glaucoma, and black and elderly people. Treatment at the early stages of glaucoma is important because damaged cells cannot be repaired.

The human eye works when light enters through the cornea, passes through the pupil, and then travels through the lens and the vitreous body to the retina and the optic nerve. The optic nerve then carries the images to the brain for interpretation. The eye produces a watery fluid called aqueous humor that nourishes the eye's internal structures. Aqueous humor is continuously produced and drained between the lens and the vitreous body. When the drainage does not keep up with the production, the fluid backs up causing increased pressure in the eye, called intraocular pressure (IOP). For decades, the traditional view of the medical profession was that glaucoma was caused by an abnormally high IOP, which pushed against the optic nerve causing it to be damaged. Treatment for glaucoma thus consisted of reducing IOP.

Research has shown that the drug brimonidine, sold by Allergan under the trade name Alphagan®, reduces IOP. Alphagan® therefore became a leading drug to treat glaucoma.

In recent years, however, the medical science view of glaucoma has changed. Scientists discovered that patients with lower IOP's were still contracting glaucoma. Some evidence has since shown that the disease may originate from the optic nerve itself. Scientists are now increasingly thinking of glaucoma as a neurodegenerative disease.

In the early 1990's, Allergan scientists discovered that brimonidine had neuroprotective properties such that applying it to nerve cells make them less susceptible to injury and degeneration than those not treated with brimonidine. Thus, Alphagan® may be a potent treatment for glaucoma as a neuroprotective agent under this new view of the disease.

B. New Drug and Generic Drug Application Procedures

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, was adopted by Congress to address the need to bring generic drugs to the market quickly and changed the way in which the Food and Drug Administration (FDA) approved the manufacture and use of new and generic drugs. *See Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed.Cir.1997). One of the most important aspects of the Hatch-Waxman Act was to "make available more low cost generic drugs." *Id.* (quoting H.R.Rep. No. 98-857(I), at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647-48).

In order to market a new drug, the maker of the drug must obtain approval from the FDA. 21 U.S.C. § 355(a). In order to obtain FDA approval, the maker must submit a New Drug Application (NDA) which includes extensive information and testing of the new drug to insure its safety. See 21 U.S.C. § 355(b). Once the NDA is approved, the holder of an approved NDA is automatically granted a five-year period of exclusivity in marketing its drug. 21 U.S.C. § 355(c)(3)(D)(ii). That period of exclusivity is extended by an additional six months if the maker conducts certain tests to insure its safety and efficacy in children. 21 U.S.C. § 355a(a)(1)(i). During this period of exclusivity, the FDA may not grant any other drug maker a license to manufacture and sell the same drug or its bioequivalent. This period of exclusivity is intended to recognize the efforts and costs that the drug maker undertook in the first place to test and insure the safety and efficacy of a new, or pioneer, drug.

Near the end of that period of exclusivity, a drug maker may file an Abbreviated New Drug Application (ANDA). *See* 21 U.S.C. § 355(j). A party submitting an ANDA need only show that the proposed new drug is the same, or the bioequivalent, of the pioneer drug.

During the ANDA process, a generic drug maker must certify that the pioneer drug is either: (i) not patented (Paragraph I Certification); (ii) protected by a patent that has expired (Paragraph II Certification); (iii) patented, but setting forth the date the patent will expire (Paragraph III Certification); or (iv) that the pioneer drug's patent is either expired or will not be infringed by the generic drug (Paragraph IV Certification). *See* 21 U.S.C. § 355(j)(2)(A)(vii). An ANDA with either Paragraph I or II certification may be quickly approved and marketed as soon as all regulatory requirements are met. An ANDA with Paragraph III Certification may not be approved until the relevant patents have expired.

Paragraph IV Certification, however, creates a different set of procedures. Under Section 202 of the Hatch-Waxman Act, Congress has specifically exempted a party that uses a patent in order to prepare an application for commercial marketing of a drug from liability for infringement. 35 U.S.C. § 271(e)(1). However, the submission of an ANDA is an act of infringement. 35 U.S.C. § 271(e)(2)(A). This infringement is "highly artificial." *See Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 676, 110 S.Ct. 2683, 2691, 110 L.Ed.2d 605 (1990). Congress enacted this statutory scheme in order to allow generic drugs to come to the market as quickly as possible. *See id.* By allowing a generic drug maker to use the patent as it prepares to obtain FDA approval, the drug maker can bring the generic drug to market as soon as the patent expires, rather than waiting for the patent to expire before undertaking years of regulatory hurdles. By the same token, allowing the filing of the ANDA to amount to an act of

infringement, the validity of a patent can be challenged before the drug comes to market. A party submitting an ANDA with a Paragraph IV Certification must inform the drug and patent owner of the application. *See* 21 U.S.C. § 355(j)(2)(B)(i). The patent owner then has 45 days in which to file an action for infringement, the basis of which is the "artificial" act of infringement of filing an ANDA. If the patent-holder does not sue for infringement, the ANDA may be quickly approved and marketed as soon as all regulatory requirements are met. If the patent-holder does file suit, the ANDA may not be approved until either the date that the Court determines either invalidity or non-infringement, the date the patent expires, or 30 months (subject to modification by the Court) after the ANDA patent holder receives notice of the Paragraph IV Certification.

C. Allergan's NDA for Alphagan® (Brimonidine)

On September 6, 1996, Allergan obtained FDA approval of its NDA, granting approval for the manufacture and sale of Alphagan® for reducing IOP, in accordance with a specific set of labeling instructions. Allergan was entitled to a five year period of exclusivity under 21 U.S.C. § 355(c)(3)(D)(ii) and an additional six month period under 21 U.S.C. § 355a(a)(1)(i). Brimonidine, however, was not protected by a patent, and thus Allergan's period of exclusivity was originally set to expire March 6, 2002.

Before that time elapsed, however, Allergan scientists discovered the neuroprotective properties of brimonidine. Accordingly, in 1999 and 2000, Allergan applied for patents covering this new use of brimonidine. In 2001, Allergan was granted U.S. Patents Nos. 6,194,415 (the '415 Patent) and 6,248,741 (the '741 Patent), both of which are continuations in part of U.S. Patent No. 5,856,329 (the '329 Patent).

The '415 and the '741 Patents (the patents at issue in this case) both claim a method of using brimonidine for treating

ocular neural injury. During the prosecution of the patents at issue, Allergan initially attempted to claim the use of brimonidine to reduce IOP. The patent examiner rejected those claims as being obvious. Allergan then limited its claims to a method of using brimonidine as a neuroprotective agent to treat glaucoma. Allergan then listed the patents in the "Orange Book," a record maintained by the FDA to provide notice to manufacturers of generic drugs that the maker of an approved new drug claims that the drug is also protected under the patent laws.[1]

In October 2001, Alcon filed an ANDA with the FDA, seeking to sell a generic brimonidine solution for use in reducing IOP with the same FDA labeling requirements approved for Alphagan®. Because the '415 and the '741 Patents were both listed in the Orange Book, Alcon filed a Paragraph IV Certification claiming that its drug was non-infringing or that the patents were invalid. Alcon notified Allergan on November 29, 2001 and Allergan brought suit within the statutorily required 45 days on January 9, 2002. Alcon now moves for summary judgment based on its argument that its proposed generic drug, labeled for use as an IOP reducing agent, but not as a neuroprotective agent, does not infringe the patents at issue.

The result of listing the '415 and '741 Patents in the Orange Book was obviously advantageous to Allergan. Under the terms of its NDA approval, its five year period of exclusivity for the sale of brimonidine under the name Alphagan® would have expired in March 2002. If, however, it can successfully claim protection under the Patent Act, it will be able to retain exclusive rights to brimonidine for the twenty year period prescribed under the Patent Act, through

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[1] Listing in the "Orange Book" is entitled to no presumption about the validity of the drug or patent owner's claims, and is a ministerial act on the part of the FDA. *See Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 10 F.Supp.2d 446, 456 (D.N.J.1998).

2015. If successful in this litigation, Allergan will retain the exclusive rights to manufacture brimonidine, even when the proposed use by Alcon is for reduction of IOP. Allergan will effectively be able to retain the exclusive rights to use brimonidine for a purpose that the Patent Office determined that it could not patent.

II.

LEGAL STANDARD

Summary judgment is proper if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c).

The Court must view the facts and draw inferences in the manner most favorable to the non-moving party. *United States v. Diebold, Inc.*, 369 U.S. 654, 655, 82 S.Ct. 993, 994, 8 L.Ed.2d 176 (1962). However, the existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; to defeat the motion, the non-moving party must affirmatively set forth facts showing there is a genuine issue for trial. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-49, 106 S.Ct. 2505, 2510, 91 L.Ed.2d 202 (1986). The moving party bears the initial burden of demonstrating the absence of a genuine issue of material fact for trial. *Id.* at 256, 106 S.Ct. at 2514. When the non-moving party bears the burden of proving the claim or defense, the moving party can meet its burden by pointing out the absence of evidence of a genuine issue of material fact from the non-moving party. *Vivid Techs., Inc. v. Am. Science & Eng'g, Inc.*, 200 F.3d 795, 806-07 (Fed.Cir.1999). The moving party need not disprove the other party's case. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-25, 106 S.Ct. 2548, 2553-54, 91 L.Ed.2d 265 (1986).

When the moving party meets its burden, the "adverse party may not rest upon the mere allegations or denials of the adverse party's pleading, but the adverse party's response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial. If the adverse party does not so respond, summary judgment, if appropriate, shall be entered against the adverse party." Fed.R.Civ.P. 56(e). "The mere existence of a scintilla of evidence . . . will be insufficient; there must be evidence on which the jury could reasonably find for [the opposing party]." *Anderson*, 477 U.S. at 252, 106 S.Ct. at 2512.

III.

DISCUSSION

A. Elements of Infringement

Determining whether there is infringement in a case requires a two step analysis. *Glaxo*, 110 F.3d at 1565. "First, the claim must be properly construed to determine its scope and meaning. Second, the claim as properly construed must be compared to the accused device or process." *Carroll Touch, Inc. v. Electro Mech. Sys., Inc.*, 15 F.3d 1573, 1576, (Fed.Cir.1993). Claim construction is a question of law for the Court to determine in the first instance. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979-81 (Fed.Cir. 1995) (en banc), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Once the claim is properly construed, determining whether a particular device infringes the patent is a question of fact. *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1569 (Fed.Cir.1983). To prove infringement, a patentee must show that every limitation of the claims asserted to be infringed is found in the accused device. *Glaxo*, 110 F.3d at 1565.

B. Claim Construction

Here, there is no material dispute as to the claims of the patents at issue. Both sides agree that the patents at issue claim the neuroprotective use of brimonidine, but not its use to reduce IOP.[2]

C. Infringement Under Section 271(e)(2)

"Allergan contends that defendants have and will infringe at least Claim 2 of the '415 patent and Claim 1 of the '741 patent." (Allergan's Mem. of P. & A. in Opp'n to Mot. for Summ. J. at 5.) Allergan's assertions of infringement are twofold. First, Allergan argues that by filing the ANDA, Alcon has committed infringement under Section 271(e)(2)(A). Second, Allergan argues that Alcon will induce infringement by doctors prescribing generic brimonidine in violation of 35 U.S.C. § 271(b).

The primary question presented in this motion is whether Allergan can, as a matter of law, bring either of these claims at this time. If it can, the record currently before the Court is sufficient to present a triable issue of fact, or at the least, allow Allergan to conduct discovery under Federal Rule of Civil Procedure 56(f) before its claim is adjudicated.

This question of law, however, is one of nearly first impression. The Court is aware of only two cases in the country, neither reported, that have squarely addressed the issue of whether a holder of a patent for a method of using a drug in the public domain can sue a generic manufacturer for infringement based solely on filing an ANDA under Section 271(e). *See Warner-Lambert Co. v. Apotex Corp.*, No. 98 C 4293, 1999 WL 259946 (N.D.Ill. Apr.8, 1999); *see also In re*

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[2] Allergan argues that the patents at issue do not claim the use of brimonidine *solely* to reduce IOP. Although the Court does not interpret the claim in that manner, the distinction is ultimately immaterial for disposition of the present motion.

Omeprazole Patent Litigation, MDL Docket No. 1291 (S.D.N.Y. July 2, 2001) (Slip op. at 25). The problem is made worse by the somewhat awkward wording of the statute. Indeed, the Supreme Court has stated that "[n]o interpretation we have been able to imagine can transform § 271(e)(1) into an elegant piece of statutory draftsmanship." *Eli Lilly,* 496 U.S. at 679, 110 S.Ct. at 2693. Therefore, to fully understand the extent of Section 271(e), a brief review of its history and purpose are appropriate.

1. Legislative Background of the Hatch-Waxman Act and Section 271(e)(2)

The Hatch-Waxman Act encompassed two different legislative issues that developed during the late 1970's. The first problem addressed by the bill was a method for bringing popular generic drugs to the market more quickly. H.R. Rep. No. 98-857(I) at 14, 1984 U.S.C.C.A.N. at 2647. The regulatory delay in bringing new generic drugs to the market keeps drug prices artificially high. The higher prices had particularly negative affects on senior citizens and drove up the cost of federal medicare and medicaid programs. *Id.* at 19-21, 1984 U.S.C.C.A.N. at 2652-53. As early as 1978, the FDA had considered regulatory action to allow for some abbreviated application. *Id.* at 16, 1984 U.S.C.C.A.N. at 2649. After several years of waiting, Congress took action itself just prior to the 1984 Presidential Election.

The Hatch-Waxman Act also responded to complaints by patent owners that the patent term for certain products, such as drugs, was effectively eroded because patent holders could not exploit their inventions while the drugs went through the long period of regulatory approval. H.R.Rep. No. 98-857(II) at 3 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2687; *see also Eli Lilly*, 496 U.S. at 669, 110 S.Ct. at 2688.

Attempts to address this problem had lingered since the 96th Congress (1979-80). H.R.Rep. No. 98-857(II) at 3, 1984

U.S.C.C.A.N. at 2687. Although the Senate passed legislation covering the area in 1982, it was thwarted in the House of Representatives on procedural grounds in September 1982. *Id.*

Hearings on the generic drug aspect of the legislation were held in the Committee of Energy and Commerce, Subcommittee on Health and the Environment in July 1983. After the subcommittee favorably reported the bill, Representative Henry Waxman of California conducted extensive negotiations with representatives of both generic and brand name pharmaceutical companies that generated a compromise that addressed the generic marketing and patent term aspects. This compromise was the basic language of the bill that became the Hatch-Waxman Act. *Id.* at 4, 1984 U.S.C.C.A.N. at 2688. Nearly a year later, the full committee marked-up the bill and adopted the compromise without further hearings. H.R.Rep. No. 98-857(I) at 16, 1984 U.S.C.C.A.N. 2649.

During the intervening time, in April 1984, the Court of Appeals for the Federal Circuit issued its decision in *Roche Products, Inc. v. Bolar Pharmaceuticals. Co., Inc.*, 733 F.2d 858 (Fed.Cir.1984). There, the court rejected the argument that using a drug for testing in order to prepare an application for approval from the FDA was a non-infringing use. *Id.* at 864-65. The Federal Circuit specifically held that it was up to Congress to address this concern. *Id.* This created a second distortion to the 17 year patent term[3] because competitors could not begin testing or seeking regulatory approval for their competing generic drugs until the patents of the pioneer drugs expired and thus could not compete in the marketplace for several years. *See Eli Lilly,* 496 U.S. at 670, 110 S.Ct. at 2688.

The Hatch-Waxman Act set out to correct these two distortions. Section 201 of the Hatch-Waxman Act provided

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[3] The term of a patent has since been extended to 20 years.

for an extension of patents for certain drugs for up to five years to address the problem of the distorted patent term on the front end. *Id.* After the Federal Circuit issued its opinion in *Roche Products*, 733 F.2d 858, Section 202 was included in the bill, which added Section 271(e) to the Patent Act and was designed to address the distortion that effectively extended the patent term on the back end. *See Eli Lilly*, 496 U.S. at 671, 110 S.Ct. at 2689.

Hearings on Section 271(e) were held in the House Judiciary Committee, which was ordered to report on the bill within six weeks. H.R.Rep. No. 98-857(II) at 3, 1984 U.S.C.C.A.N. at 2687. The committee did not undertake a detailed examination of the type of claims that could be brought under Section 271(e)(2), but instead focused on whether Section 271(e)(1) amounted to an unconstitutional taking under the Fifth Amendment.[4] The Judiciary Committee reported the bill to the House on August 1, 1984.

In the intervening time, concerns about the bill were still being sounded by large pharmaceutical companies and the Patent and Trademark Office. The reservations threatened the bill's passage. *See* 130 Cong. Rec. 23,774 (1984) (statement of Sen. Baker). Senator Orrin Hatch of Utah, then chairman of the Senate Labor and Human Resources Committee, was Waxman's co-sponsor and had shepherded the bill through the Senate. In the waning days before the August recess, Hatch engaged in several marathon negotiating sessions in an effort to save the legislation. *Id.* Hatch's efforts were ultimately successful and led to several changes to the bill that kept intact its fundamental purpose of bringing generic drugs to the market quickly while maintaining broad bipartisan support. 130 Cong. Rec. 23,764 (1984). These changes included granting a five-year period of exclusivity in

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[4] The House Judiciary Committee rejected that position, and the Supreme Court appears to have agreed in *Eli Lilly*, 496 U.S. at 678, 110 S.Ct. at 2693 n. 7.

marketing of new, unpatented drugs, codified at 21 U.S.C. § 355(c)(3)(D)(ii), in order to give incentives to drug makers to develop new medications; extending the period during which the FDA has to delay approval of an ANDA if a patentee brings suit under Section 217(e)(2) from 18 to 30 months, and clarifying the FDA's authority to disapprove ANDAs that are not identical to the pioneer drugs and in cases where the FDA is taking steps to remove the pioneer drug from the market. 130 Cong. Rec. 24,425. Having reached this compromise, the House passed the measure on September 6, 1984. The Senate followed six days later, and on September 24, 1984, President Reagan signed the Hatch-Waxman Act.

2. Jurisdictional Nature of Section 271(e)

Section 271(e)(2) provides in part that "[i]t shall be an act of infringement to submit an [ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . . ." 35 U.S.C. § 271(e)(2)(A). Alcon admits[5] that its ANDA seeks approval for a drug for which Allergan has a valid patent claiming a method of use. Thus, Allergan argues that a "finding of no literal infringement . . . is potentially foreclosed in its entirety by the statute." (Allergan's Mem. of P. & A. in Opp'n to Mot. for Summ. J. at 10.) Allergan's literal reading of the statute is naturally problematic, as it would create a new and more expansive definition of infringement, and would appear to exclude traditional defenses such as invalidity and non-infringing use.[6] The Federal Circuit has

[5] Alcon's admissions are limited for use in the present motion only.

[6] At oral argument, Allergan insisted that it was not urging the Court to disregard the defense of invalidity. Nevertheless, that is the logical conclusion of Allergan's argument, as a literal reading does not encompass the invalidity defense. *Compare* 35 U.S.C. § 271(a) ("Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention . . . infringes the patent") *with* 35 U.S.C. § 271(e)(2).

also foreclosed this argument. In *Glaxo,* 110 F.3d at 1567, the Federal Circuit stated that "[t]he plain language of the statute does not alter a patentee's burden of proving infringement, nor does it mandate an infringement analysis limited to the scope of the [ANDA] approval sought."

The difficulty in a patent case brought under Section 271(e)(2) is that the allegedly infringing acts have not yet occurred. *Id.* The Court must engage in a hypothetical evaluation to determine what "is likely to be sold, or, preferably, what will be sold." *Id.* If the drug that will be sold upon approval of the ANDA is infringing, then the infringing maker will not be allowed to obtain approval of its ANDA. Ordinarily, such a hypothetical determination would run afoul of the "case or controversy" requirement of Article III. U.S. Const. art. III, § 2. Section 271(e)(2) therefore provides no new substantive law, but much like the Declaratory Judgment Act, 28 U.S.C. § 2201, merely provides a jurisdictional "hook" for a patent case. *Glaxo,* 110 F.3d at 1569 ("§ 271(e)(2) provided patentees with a defined act of infringement sufficient to create case or controversy jurisdiction. . . .")

3. Scope of Claims that Can be Brought Under Section 271(e)(2)

Allergan argues that even if the submission of an ANDA does not constitute infringement per se, the Court must focus on whether it is likely that its patents will be infringed if Alcon is allowed to market its generic brimonidine, even though Alcon would not be the party using the drug in violation of Allergan's patent rights. Allergan's arguments, and the cases it relies on, tend to conflate the concepts of direct infringement under Section 271(e)(2) and inducing infringement under Section 271(b). The Court therefore sets out these two distinct arguments.[7]

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[7] Allergan does not rely on a third possible ground, that Alcon would contributorily infringe the '415 and '741 Patents in violation of 35 U.S.C.

i. Direct Infringement

There is no question that, under a traditional infringement analysis, Alcon has not and will not infringe Allergan's patents. Alcon has made and seeks to sell the drug brimonidine, an old drug which has fallen into the public domain. As distinguished from the facts in *Glaxo*, where the plaintiff owned a patent that claimed both the compound per se and a method of creating it, *id.* at 1564, Allergan does not own a patent in the chemical brimonidine. Instead, the '415 and '741 Patents claim methods for using brimonidine. Under a traditional analysis, Allergan's patents will only be infringed if prescribing physicians use brimonidine as a neuroprotective agent, something Alcon cannot do.

Allergan's argument must therefore be based on an interpretation of the Hatch-Waxman Act as giving a pioneer drug maker/patentee a remedy against the generic drug maker for a wrong that will be committed in the future by someone else.

As set forth above, Section 271(e)(2) provides that "[i]t shall be an act of infringement to submit an [ANDA] for a drug . . . the use of which is claimed in a patent . . . ." 35 U.S.C. § 271(e)(2)(A). When looking at this language in isolation, an argument can be made that by enacting this statute, Congress was seeking to address precisely the situation now before the Court—a pioneer drug manufacturer such as Allergan invests substantial sums of money into research to find a new way to use an old drug. Although it cannot obtain a patent for the drug itself, as it has fallen into the public domain, it does obtain a patent on this new method of using

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§ 271(c), as it concedes that brimonidine has non-infringing uses, specifically the reduction of IOP. In *Sony Corp. of America v. Universal City Studios, Inc. (The Betamax Case)*, 464 U.S. 417, 441-42 104 S.Ct. 774, 788 (1984), the Supreme Court examined the doctrine of contributory infringement in the context of patent law, and held that a party cannot be held liable as a contributory infringer if it manufactures a product that is adapted to non-infringing uses.

the drug, one which may well save significant suffering. But since the product itself was not patented, the generic drug manufacturer can swoop in, mass produce the drug, and leave physicians to their own devices as to how to prescribe the medicine.

Congress, one could argue, knew that it would be both impractical and bad business for the pioneer manufacturer to sue thousands of doctors across the country for patent infringement. Thus, it set up a no-fault system, disallowing the marketing of any generic drug if there is an unexpired patent claiming a method of using that drug, thereby stopping the infringing activity before it occurs. Unfortunately for Allergan, the structure of the Hatch-Waxman Act, its legislative history, and the specific problem that Section 271(e) was meant to address do not allow for such an interpretation.

In April 1984, the Federal Circuit, in *Roche Products*, 733 F.2d 858, held that there was no "experimental use" defense to patent infringement. As the district court in *Roche Products* found, cases prior to the Federal Circuit's decision had found that such experimental use did not give rise to a claim for infringement, or at least would not require a court to issue an injunction. *Roche Prods., Inc. v. Bolar Pharms. Co., Inc.*, 572 F.Supp. 255, 258 (E.D.N.Y.1983) (citing *Kaz Mfg. Co., Inc. v. Chesebrough-Pond's, Inc.*, 211 F.Supp. 815 (S.D.N.Y.1962), *aff'd*, 317 F.2d 679 (2d Cir.1963); *Maxon Premix Burner Co. v. Eclipse Fuel Eng'g Co.*, 471 F.2d 308 (7th Cir.1972)). Congress then hastily drafted Section 271(e) to reverse the decision and complete its work on the issue before the fall election. Thus, while most of the Hatch-Waxman was considered over a period of nearly six years and through several congressional hearings, Section 271(e) was drafted and reported out of the House Energy and Commerce Committee in just over six weeks. The only congressional hearings on Section 271(e) were focused on the constitutional takings issue and not on the practical impact of the statute.

The result, unsurprisingly, is a statute which even the Supreme Court has described as something less than an "elegant piece of statutory draftsmanship" requiring courts to engage in interpretation beyond the plain language. *Eli Lilly*, 496 U.S. at 679, 110 S.Ct. at 2693 (Scalia, J.).

In *Roche Products*, the patent at issue claimed the active ingredient in a prescription sleeping pill. 733 F.2d at 860. Unlike the present case, the patent claimed only the compound itself, not the use the drug. Thus, when drafting Section 271(e), Congress was primarily focused on exempting from infringement the use of a patented drug, not the use of a patented method of using that drug.

The structure of the Hatch-Waxman Act as a whole also does not allow for Allergan's claim here. This claim arose because when Alcon submitted its ANDA for generic brimonidine, it filed a Paragraph IV Certification asserting that the patents listed in the Orange Book were either invalid or not infringed. Pursuant to the requirements of a Paragraph IV Certification, it notified Allergan of the ANDA, which gave Allergan notice that it needed to bring this suit within 45 days. Under the Hatch-Waxman Act, however, it does not appear that Alcon was even required to file a Paragraph IV Certification.

A certification under paragraphs I-IV is required to be filed "with respect to each patent which claims the listed [i.e. pioneer] drug . . . or which claims a use for such listed drug for which the applicant is seeking approval . . . ." 21 U.S.C. § 355(j)(2)(A)(vii). In its report on the bill, the House Judiciary Committee set forth the process more clearly, stating that a certification under paragraphs I-IV was required only for "product patents . . . and all use patents which claim an indication for the drug which the applicant is seeking approval." H.R.Rep. No. 98-857(II) at 13, 1984 U.S.C.C.A.N. at 2697. The Judiciary Committee described these as "Controlling Use Patents." Under this definition, it is clear that the '415 and

'741 Patents are not Controlling Use Patents, as Alcon is not seeking approval for the indications claimed in those patents.

Furthermore, the House Energy and Commerce Committee explained that:

> if there are indications which are claimed by any use patent and for which the applicant is not seeking approval, then an ANDA must state that the applicant is not seeking approval for those indications which are claimed by such use patent. For example, the listed drug may be approved for two indications. If the applicant is seeking approval only for indication No. 1, and not indication No. 2 because it is protected by a use patent, then the applicant must make the appropriate certification [under paragraphs I-IV] and a statement explaining that it is not seeking approval for indication No. 2.

H.R.Rep. No. 98-857(I) at 22, 1984 U.S.C.C.A.N. at 2656; *see also* 21 U.S.C. § 355(j)(2)(A)(viii). The example given by the House Energy and Commerce Committee is nearly identical to the situation now before the Court. Alcon is seeking approval to market brimonidine only for one indication, reducing IOP, and not for the second indication, as a neuroprotective agent,[8] because it is protected by a patent. Alcon therefore was not required under the law to file a Paragraph IV Certification.[9] It is the filing of a Paragraph IV Certification that puts into process the notice to the patentee

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[8] In the present case, however, the second indication for using brimonidine as a neuroprotective agent is not even approved by the FDA.

[9] As a practical matter, however, filing the Paragraph IV Certification was the most prudent route given that the '415 and '741 Patents were listed in the Orange Book. It is worth noting that the regulations issued by the FDA suggest that the '415 and '741 Patents should not have even been listed in the Orange Book. The regulations, found at 21 C.F.R. § 314.53(b) provide that "[f]or patents that claim a method of use, the applicant shall submit information only on those patents that claim indications or other conditions of use of a pending or approved application."

allowing it to bring suit under Section 271(e)(2). It does not withstand scrutiny to conjecture that Congress intended to design a system where a patentee could bring suit to prevent the approval of an ANDA in cases where it did not require the ANDA applicant to notify the patentee.

Infringement actions under Section 271(e)(2) must therefore be limited to the Controlling Use Patents. An ANDA which seeks approval only for indications that are not claimed in a patent does not violate Section 271(e)(2). Because there are no such Controlling Use Patents here, Alcon's ANDA does not directly infringe the '415 of '741 Patents.

ii. Inducing Infringement

Allergan alternatively argues that even if direct infringement cannot be shown, it has a right to prove that Alcon will, by sale of its generic brimonidine, induce infringement of the '415 and '741 Patents. Allergan claims that doctors who currently prescribe Alphagan® as a neuroprotective agent will prescribe Alcon's generic brimonidine not just to reduce IOP, but also for its neuroprotective use, thereby infringing Allergan's process patent.

Section 271(e), however, does not provide a predicate for Allergan to sue for inducing infringement. Although Allergan argues that Section 271(e) was enacted by Congress to provide a mechanism to adjudicate the issues of infringement before the generic drug comes to market, the purpose and effect of Section 271(e) is not so broad as Allergan would suggest.

Section 271(e) was designed to address the distortion to the end of the patent term that effectively extended a patentee's period of exclusivity. *Eli Lilly*, 496 U.S. at 671, 110 S.Ct. at 2689. Section 271(e)(1) exempts a party from liability for infringement if it makes, uses or sells a patented drug solely for the purpose of developing a generic drug to obtain regulatory approval. 35 U.S.C. § 271(e)(1). Section 271(e)(2),

however, creates what the Court has called a "somewhat artificial [ ] act of infringement," *Eli Lilly*, 496 U.S. at 676, 110 S.Ct. at 2691, when a party files an application to use that drug. 35 U.S.C. § 271(e)(2). The result is to bar a patent holder from suing for infringing use during the development and testing stage, but allow the patentee to sue under an expedited process once the infringer files for approval of the drug. Thus, what Congress taketh away in Section 271(e)(1), it giveth in Section 271(e)(2). The Court must therefore conclude that the type of claims that accrue upon the filing of an ANDA are limited to those claims that would have accrued earlier, when a generic drug maker used the patent to develop its generic drug.[10]

Viewed as such, a patent-holder cannot bring a claim under Section 271(e)(2) that the generic drug maker will, upon approval of the patent, induce others to infringe. As Allergan points out, the elements for inducing infringement are infringement by a third-party and "intent to encourage another's infringement." *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed.Cir.1990); *see also* 35 U.S.C. § 271(b). Had Section 271(e) not been enacted, Allergan in this case would have been able to sue Alcon for infringement for using its patent in the development of a generic drug. It could not, however, sue Alcon for inducing infringement because there was yet to be any third-party infringement and thus the question of inducing infringement would be entirely too speculative.[11]

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[10] Allergan contends that this view of Section 271(e)(2) improperly looks backwards in time whereas *Glaxo* requires the Court to look to what will happen in the future. 110 F.3d at 1570. This is a misunderstanding of the Court's analysis. The Court is not looking backwards to determine whether there had been infringement, but merely looking backwards to see what causes of action Congress determined were justiciable under the Hatch-Waxman Act.

[11] Allergan argues that prior to the Hatch-Waxman Act, Alcon would have had to conduct clinical trials and distribute the drug to hundreds of

Allergan's argument that Section 271(e)(2) is the predicate act of infringement is circular. The only predicate act of infringement that Allergan alleges is Alcon's own filing of the ANDA.[12] Allergan argues that this allows the Court to examine what acts of infringement, including inducing infringement, Alcon will commit.

Allergan points to two unpublished district court decisions that it contends support its argument. *See Warner-Lambert,* 1999 WL 259946;[13] *see also In re Omeprazole Patent Litig.,* MDL Docket No. 1291 (citing *Warner-Lambert,* 1999 WL 259946, at *3). Both cases, like Allergan's argument here, conflate the issue of infringement under Section 271(e)(2) and the predicate act of infringement necessary to support a claim for inducing infringement. The district court in *Warner-Lambert* stated:

> Except for the district court's use of an *a priori* viewpoint, the court's "inquiry in a suit brought under § 271(e)(2) is the same as it is in any other infringement suit. . . ." Thus, in support of a suit brought under section 271(e)(2), a patent owner may rely on the theory that the commercial manufacture, use, or sale of a drug claimed

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doctors to use, thereby inducing their infringement. The argument fails because that type of inducing infringement would not be speculative. The underlying infringing acts and the acts inducing the infringement would have already happened and the Court would not be forced to speculate on future actions by parties.

[12] It is undisputed that no prescribing physician has infringed Allergan's patents in either a traditional manner or by filing an ANDA.

[13] *Warner-Lambert* is not entirely favorable to Allergan, as the district court there, in a subsequent decision in that case, found that a claim for literal infringement under Section 271(e)(2) was foreclosed. *Warner-Lambert Co. v. Apotex Corp.,* No. 98 C 4293, 2001 WL 1104618, *3 n. 3 (N.D.Ill. Sept.14, 2001).

> in a patent or the use of which is claimed in a patent will actively induce the infringement of the owner's patent.

1999 WL 259946, at *3 (quoting *Glaxo,* 110 F.3d at 1569). While correct that the Court's inquiry under Section 271(e)(2) must be the same as in any other infringement suit, the remainder of this statement is erroneous for four reasons. First, the "exception" that the district court notes is a very important one indeed. As a practical matter, the *a priori* viewpoint of the Court requires it to speculate into what promotional efforts Alcon will undertake if its ANDA is approved and whether the physicians will then actually infringe the patent by prescribing its use as a neuroprotective agent. The speculation is not only practically difficult, but is constitutionally problematic. Because there has not been even a predicate act of infringement by the prescribing physicians, there is not a sufficiently immediate threat that there will be a violation of the patent laws so as to warrant judicial determination. *See Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273, 61 S.Ct. 510, 512, 85 L.Ed. 826 (1941). Thus, allowing a patentee to bring a claim for inducing infringement under Section 271(e)(2) runs afoul of the "case or controversy" requirement of Article III. U.S. Const. art. III, § 2.

Second, *Warner-Lambert* and *Omeprazole* both give a broad construction to Section 271(e)(2), yet it is well settled that "[s]tatutes purporting to confer federal subject matter jurisdiction must be narrowly construed, with ambiguities resolved against the assumption of jurisdiction." *Mars Inc. v. Kabushiki-Kaisha Nippon Conlux*, 24 F.3d 1368, 1373 (Fed.Cir.1994). Thus, even if a district court could, consistent with Article III, hear a case of inducing infringement when there has not yet been any third-party infringement, Congress must make a very explicit grant of jurisdiction. Section 271(e)(2) provides no such explicit grant.

Third, the court in *Warner-Lambert* did not examine Section 271(e) in light of the entirety of the Hatch-Waxman Act. The court there stated that "[n]owhere does the statute require that the proposed use of the generic drug be within the scope of the uses claimed in the patent in question for infringement to occur." 1999 WL 259946, at *3. This statement is plainly erroneous. Although it is not specifically stated in Section 271(e)(2), the Hatch-Waxman Act includes exactly this requirement, as the Court has set forth in part III.C.3.i, *supra.* In addition, Section 271(e)(4)(A) provides that the exclusive remedy for this case brought under Section 271(e)(2) is to delay FDA approval of the ANDA until the patents at issue expire. Even Allergan admits that the mere production of generic brimonidine does not infringe its patents, but that it must prove that Alcon has taken steps that would actively induce infringement. Yet the remedy for cases under Section 271(e)(2) would prevent the production of generic brimonidine and not address at all Alcon's active inducement. The result is akin to using a sledgehammer to squash an ant. If Congress had intended for Section 271(e)(2) to allow a claim for inducing infringement, it is fair to assume the remedy it prescribed would address the inducement.

Finally, neither the of the district courts in *Warner-Lambert* nor in *Omeprazole* examined the purpose of the Hatch-Waxman Act that created Section 271(e). As set forth above, the purpose of the Hatch-Waxman Act was to bring low cost generic drugs to market more quickly by exempting certain research uses from patent infringement liability, while still providing a jurisdictional "hook" for patentees to make their infringement claims before the drugs come to market. Accepting the interpretation of Section 271(e)(2) urged by Allergan, and adopted by the *Warner-Lambert* and *Omeprazole* courts, would not only allow a patentee to sue for those acts of infringement that, prior to the Hatch-Waxman Act, the patentee could have brought during the development of the drug, but would also allow the patentee to

sue for inducing an infringement that has not yet occurred. This interpretation turns the Congress's intent on its head. It would allow a pioneer drug manufacturer greater remedies than it had prior to the Hatch-Waxman Act and would allow them to block the manufacture of generic drugs by claiming inducing infringement whereas prior to the Hatch-Waxman Act, they could not.[14]

IV.

CONCLUSION

Accordingly, Alcon's motion for summary judgment on Allergan's complaint is GRANTED.

IT IS SO ORDERED.

---

[14] The result might be even more perverse in the present case, because if Allergan were to succeed, it would be able to effectively monopolize the market on all manufacture and use of brimonidine even though it admittedly can have no patent on the manufacture of brimonidine, and only has a patent on one of many uses for the drug.

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

02-1449

ALLERGAN, INC. AND ALLERGAN SALES, INC.,
Plaintiffs-Appellants,

v.

ALCON LABORATORIES, INC., ALCON RESEARCH, LTD.,
AND ALCON UNIVERSAL, LTD.,
Defendants-Appellees,

and

BAUSCH & LOMB INCORPORATED,
Defendant-Appellee.

Decided: May 22, 2003

ORDER

A petition for rehearing en banc having been filed by the APPELLANT,* and a response thereto having been invited by the court and filed by the APPELLEE, and the matter having first been referred as a petition for rehearing to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service.

---

* Amicus curiae briefs were filed by:

1 - Generic Pharmaceutical Association.

2 - Washington Legal Foundation.

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on May 29, 2003.

(2)

No. 03-443

Supreme Court, U.S.
FILED
OCT 2 4 2003
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

ALLERGAN, INC. and ALLERGAN SALES, INC.,

Petitioners,

v.

ALCON LABORATORIES, INC., ALCON RESEARCH, LTD., ALCON UNIVERSAL, LTD., and BAUSCH & LOMB INCORPORATED,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION FOR RESPONDENTS ALCON LABORATORIES, INC., ALCON RESEARCH, LTD., AND ALCON UNIVERSAL, LTD.

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COUNTER-STATEMENT OF THE QUESTION PRESENTED

Whether the U.S. Court of Appeals for the Federal Circuit properly affirmed a judgment limiting pre-market patent infringement suits under 35 U.S.C. § 271(e)(2) to patents that claim the use for which an Abbreviated New Drug Application ("ANDA") seeks approval, and thus dismissed the instant case where:

(a) respondents' ANDA sought approval to make and sell generic brimonidine for the single indication of lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension;

(b) neither the product brimonidine nor the method of using it for lowering intraocular pressure was covered by any patent; and

(c) petitioners' asserted patents claim a method of using brimonidine (for neuroprotection) that has not been subject to clinical trials and thus has never been approved by the FDA.

CORPORATE DISCLOSURE STATEMENT

Respondents Alcon Laboratories, Inc. and Alcon Research, Ltd. are wholly owned by Alcon, Inc. (formerly known as Alcon Universal, Ltd.). Respondent Alcon, Inc. has no parent company and Nestle, SA is the only publicly held company that owns 10% or more of its stock.

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1 Donald S. Chisum, Chisum on Patents, § 1.03[8][c] (2003) 21

STATUTES AND REGULATIONS INVOLVED

In addition to 35 U.S.C. § 271(e)(2), set forth in petitioners' brief, the following provisions are pertinent to the question presented:

Title 35 U.S.C. § 271(e)(4) provides, in relevant part, that:

> For an act of infringement described in paragraph [271(e)](2)—
>
> (A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed. . . .

Title 21 U.S.C. § 355(b)(1) provides, in relevant part, that:

> The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacturer, use, or sale of the drug.

Title 21 U.S.C. § 355(j)(2)(A)(vii) and (viii) provide, in relevant part:

> An abbreviated application [ANDA] for a new drug shall contain—
>
> * * *

> (vii) a certification . . . with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval . . .
>
> * * *
>
> > (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the application is submitted; and
>
> (viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

Title 21 C.F.R. § 314.53(b), entitled "Patents for which information must be submitted," states, in relevant part:

> An applicant . . . shall submit information on each patent that claims the drug or a method of using the drug that is the subject of the new drug application . . . and with respect to which a claim of patent infringement could reasonably asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. . . . For patents that claim a method of use, the applicant shall submit information only on those patents that claim indications or other conditions of use of a pending or approved application.

COUNTER-STATEMENT OF THE CASE

A. Introduction

Fundamental to this case is whether Congress intended to authorize patentees to institute patent infringement actions under 35 U.S.C. § 271(e)(2) against applicants seeking FDA approval through the ANDA process to market generic drugs, based upon method-of-use patents that concededly do not claim the method of using the drug for which ANDA approval is being sought. The Federal Circuit examined this question in *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003), *see* Appendix ("App."), *infra*, 1a-33a, and properly held that the Act does not expand the scope of traditional patent law so as to broaden the rights of patentees with respect to method-of-use patents that would not be infringed in the conventional sense by use of the drug in the method for which ANDA approval is sought.

The *Warner-Lambert* court held that § 271(e)(2) authorizes infringement actions only on patents that claim use of a drug in the same method as that for which the generic applicant seeks approval (*i.e.*, what Congress described as "controlling use patents"). In doing so, the *Warner-Lambert* court rejected the argument that New Drug Application ("NDA") holders can prevent generic competition for unpatented uses of unpatented drugs based on the future possibility that third parties will use the drug for a use that would infringe a method-of-use patent that claims an unapproved ("off-label") use. Because an ANDA applicant can only seek approval of products or methods of using products that have been previously approved after safety and efficacy testing, this interpretation of the Act fosters Congress's stated purpose "to make available more low cost generic drugs [and] to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket approval." *See* Drug Price Competition and Patent Term Restoration Act

of 1984, H.R. Rep. No. 98-857(I), at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647-48.

While the decision in this case included concurring opinions on behalf of each of the panel members that criticized the *Warner-Lambert* holding, the panel recognized and properly followed the holding of the *Warner-Lambert* court in affirming the summary dismissal of petitioners' complaint by the district court. Petitioners' subsequent petition for rehearing and rehearing *en banc* was denied without dissent, leaving no uncertainty in the governing rule of law, which is entirely consistent with prior precedent of this Court and the Court of Appeals for the Federal Circuit.

B. Statutory Background

To obtain FDA approval to manufacture a new drug, the applicant must submit an NDA supported by clinical trials that prove the safety and efficacy of the proposed drug for a specific treatment or indication. Under the Act, generic drug makers may submit an ANDA which relies on the safety and efficacy studies supporting the NDA. To further encourage the prompt marketing of generic drugs, Congress amended the patent laws to free generic manufacturers from liability for patent infringement in connection with the developmental work for ANDA's. *See* 35 U.S.C. § 271(e)(1). Thus, the generic version of a drug may be tested to prepare an ANDA while a relevant patent is still in effect. This allows the ANDA to be ready for approval and the generic drug to be marketed immediately upon expiration of the relevant patent.

Congress also sought to encourage the commercial development of new drugs by creating incentives for NDA applicants. The Act creates a period of market exclusivity to compensate NDA-holders for their investment in the safety and efficacy studies necessary to obtain FDA approval. Thus, an NDA-holder for a new drug is awarded five years

of market exclusivity for its new drug, without regard to its patented status. 21 U.S.C. § 355(c)(3)(D)(ii). Additional testing to prove the safety and efficacy of the drug in children may earn the NDA-holder an additional six months of market exclusivity. 21 U.S.C. § 355a(a)(1)(A)(i). During the period of exclusivity, the FDA may not approve any other applicant to manufacture and sell the drug or its bioequivalent (*i.e.*, generic version). 21 C.F.R. § 314.108(b). A supplemental NDA for a new use for an approved drug is awarded three years of exclusivity.[1] 21 U.S.C. § 355(c)(3)(D)(iv) and 21 C.F.R. § 314.108(b)(5)(ii).

As a further incentive for those NDA-holders who bring a patented product to market, the Act restores some of the time lost on patent life as a result of the lengthy FDA approval process by permitting one extension of the earliest patent on certain products subject to "pre-market approval." 35 U.S.C. § 156.[2] The Act also provides that, although generic manufacturers may prepare ANDA's free from the cloud of infringement liability, they may not commercialize their products prior to the expiration of relevant patents. 35 U.S.C. § 271(e)(2)(A). This scheme depends entirely on NDA-holders submitting any patent that covers the approved drug or an approved use of the drug to the FDA for publication in "Approved Drug Products with Therapeutic Equivalence

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1. Petitioners argue that this exclusivity is worthless where a generic drug is approved for a another use of the same drug. (Petitioners' Brief ("P. Br.") at 18). That issue however is not presented in this case, where there is only one approved use of brimonidine, and it is unpatented. Petitioners' attempt to insert, at this stage, an issue that was neither raised nor decided below is improper.

2. The patent term extension provision is not relevant to this case because petitioners never had a patent on brimonidine or on the use for which they sought FDA approval.

Evaluations," commonly referred to as the "Orange Book." 21 U.S.C. § 355(b)(1) and (c)(2); 21 C.F.R. § 314.53(b).[3]

Pursuant to the Hatch-Waxman Act, for each patent that is listed in the Orange Book *and* that "claims a use for such listed drug for which the applicant is seeking approval," the ANDA applicant must certify that: (I) no such patent information has been filed; (II) the patent has expired; (III) the manufacturer will not commence marketing until after such patent has expired; or (IV) such patent is invalid or will not be infringed by the manufacture and sale of the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii). A further section requires that for patents listed in the Orange Book that do not claim the use for which the ANDA seeks approval, the applicant make a statement to that effect. 21 U.S.C. § 355(j)(2)(A)(viii).

Once an ANDA is submitted with a paragraph IV certification, the applicant must give notice to the NDA-holder who may then commence an infringement suit under 35 U.S.C. § 271(e)(2). However, for a patent "which claims no uses for which the applicant is seeking approval," the notice requirement does not apply. 21 C.F.R. § 314.95(a)(3). If the NDA-holder brings suit within 45 days of receiving notice, the ANDA approval is automatically stayed for a period of up to 30 months or until a court decision of invalidity or non-infringement is obtained. 21 U.S.C. § 355(j)(5)(B)(iii). If infringement is found, the approval of the ANDA is stayed for the unexpired life of the infringed patent. 35 U.S.C. § 271(e)(4).

This complexly balanced statutory scheme is distorted when, as here, patents that do not cover the approved use of

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3. The listing of a patent in the Orange Book is entitled to no presumption about the propriety of that listing, and is merely a ministerial act on the part of the FDA. *See Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 10 F. Supp.2d 446, 456 (D.N.J. 1998).

a drug are improperly listed in the Orange Book and are asserted under § 271(e)(2) to prevent FDA approval of an ANDA.

C. Petitioners' NDA

After having invested in clinical trials to prove the safety and efficacy of Alphagan®, a 0.2% concentration of brimonidine tartrate solution ("brimonidine"), for its use in "lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension," petitioners filed an NDA, which was approved by the FDA on September 6, 1996. Petitioners' investment in obtaining the NDA was rewarded under the Act by five and one-half years of market exclusivity for Alphagan®. *See* 21 U.S.C. § 355(c)(3)(D)(ii); 21 U.S.C. § 355a(a)(1)(A)(i). Petitioners received the exclusive right to market brimonidine for that period of time even though petitioners had no patents on brimonidine or its use for lowering intraocular pressure ("IOP"). Petitioners' market exclusivity on Alphagan® expired on March 6, 2002.

D. Petitioners' Orange Book Listings

In the early 1990's, petitioners' scientists allegedly discovered that brimonidine had neuroprotective properties useful to treat glaucoma and obtained two patents on that purported new use of the drug.[4] These patents were unsupported by clinical trial results, which are not necessary

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4. There is no support in the record for petitioners' assertion that "the vast majority of glaucoma patients are candidates for neuroprotective treatment" or that "the patented use is the substantial use for the drug." (P. Br. at 8 and 24).

for patentability of an invention.[5] Moreover, it is undisputed that petitioners have not performed the clinical trials necessary to obtain FDA-approval for this purported new use of the drug.

In 2001, just as their period of market exclusivity for Alphagan® was ending, petitioners listed two patents on neuroprotection in the Orange Book as patents which purportedly covered the approved use of the drug (lowering of IOP). However, it is a conceded fact that petitioners' patents claim only the unapproved neuroprotective use of brimonidine. Petitioners' Appendix ("Pet. App.") 53a. Thus, petitioners' patent listings were in violation the statutory listing provision and the pertinent FDA regulation. *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(b).

E. Respondents' ANDA

In mid-2001, respondents filed an ANDA seeking approval to market generic brimonidine for its only FDA-approved use, lowering IOP. Because petitioners had listed patents in the Orange Book as supposedly covering the approved use of its drug, and because FDA does not evaluate the propriety of patent listings, respondents were forced to certify to those patents, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), even though the ANDA sought approval only for the unpatented FDA-approved use of brimonidine for lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension. Petitioners then asserted that the filing of respondents' ANDA with a Paragraph IV certification was

---

5. There is no support in the record for petitioners' assertion that they have spent 10-15 million dollars researching the neuroprotective use of brimonidine. The fact that this unsupported statement is juxtaposed with petitioners' explanation of how pioneer drug makers must do expensive research "to develop new uses for FDA-approved drugs" should not be mistaken for petitioners making the necessary investment to obtain FDA approval for such new use. That is something petitioners did not do. (P. Br. at 15).

an act of infringement under § 271(e)(2) and sued respondents causing FDA approval of respondents' ANDA to be automatically stayed.[6] 21 U.S.C. § 355(j)(2)(A)(viii).

F. The District Court Ruling

Respondents promptly moved for summary judgment of non-infringement in petitioners' suit. Noting that the FDA regulations "suggest that [petitioners' patents] should not even have been listed in the Orange Book," the district court granted the motion and correctly held that "the structure of the Hatch-Waxman Act as a whole [] does not allow for [petitioners'] claim here." Pet. App. 61a. That court recognized that petitioners were seeking "to effectively monopolize the market on all manufacture and use of brimonidine even though [they] admittedly can have no patent on the manufacture of brimonidine, and only have a patent on one of many uses for the drug." Pet. App. 68a n.14. Indeed, in granting respondents' motion, the court stated: "[Petitioners'] interpretation [of the Hatch-Waxman Act] turns Congress's intent on its head." Pet. App. 68a. Petitioners appealed to the Federal Circuit.

G. The Federal Circuit Affirmance And Denial Of Rehearing *En Banc*

The Federal Circuit unanimously affirmed the district court's grant of respondents' motion for summary judgment. Although the *Allergan* court appropriately followed the controlling Federal Circuit precedent in *Warner-Lambert*, App. *infra*, 1a to 33a, the panel criticized that decision in two concurring opinions. Judge Schall authored a concurring opinion (in which Judge Clevenger joined) indicating that his preferred construction of § 271(e)(2) would have

---

6. Bausch & Lomb, Inc. ("B&L") also filed an ANDA for the use of brimonidine to reduce IOP. B&L was also sued by petitioners and FDA approval of its ANDA was stayed.

permitted a suit based on a patent which claims only an unapproved use of a drug. Pet. App. 22a to 41a. Judge Linn authored a separate concurrence consistent with Judge Schall's construction of the statute. Pet. App. 42a to 44a.

While reaching the correct result, the *Allergan* panel made several fundamental errors in its analysis. At the outset, the *Allergan* panel mistook the existence of petitioners' patents for proof that the drug was "effective" for the patented use. Pet. App. 2a. That conclusion was an error of law: Drug patents do not require proof of safety and efficacy, which may only be determined by the FDA (not the PTO) on the basis of well-controlled clinical trials. 21 U.S.C. § 355(d). It is undisputed that petitioners have not obtained an NDA (FDA approval) for their patented use of brimonidine. Judge Schall then proceeded to improperly balance the rights of "patentees," instead of the rights of NDA-holders, against those of ANDA applicants. Pet. App. 26a. In addition to those errors, Judge Schall's interpretation of the Act was based on his "plain language" construction of a solitary fragment of one section of a complex statutory scheme, without regard to contradictory statutory provisions and regulations or reference to the statutory scheme as a whole. In fact, Judge Schall summarily discounted other sections of the Act and pertinent sources of statutory construction as inconsistent with his initial interpretation.

Relying on the panel's concurring opinions, petitioners sought rehearing of their appeal by the Federal Circuit en banc. The full court denied *en banc* rehearing, without published dissent.

REASONS FOR DENYING THE PETITION

"A petition for a writ of *certiorari* will be granted only for compelling reasons," *see* SUP. CT. R. 10, but there is nothing deserving of the Court's review in this case. First, the case was properly decided by the court below. The Federal Circuit's controlling interpretation of § 271(e)(2) in *Warner-Lambert*, which recognized and preserved the balance struck by Congress in the Act between encouraging investment in the development of new drugs, and facilitating the public's access to low cost generic drugs through the ANDA process, was properly followed by the *Allergan* court in affirming below.

Second, there is no conflict among the circuit courts of appeal given the exclusive jurisdiction of the Federal Circuit and there is no uncertainty or lack of clarity within the Federal Circuit with regard to the issue presented, as the decision below acknowledges. Although the *Allergan* panel issued concurring opinions critical of the *Warner-Lambert* decision, no dissenting opinion issued when the full court denied petitioners' petition for rehearing *en banc*. There was no departure from Federal Circuit precedent that merited a rehearing *en banc* or that raises issues properly of concern in this Court. *See* SUP. CT. R. 10(a).

Third, the legal significance of this case has greatly diminished since its filing because of the new FDA implementing regulations that were published after the case was decided below. *See* Applications for FDA Approval To Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays On Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed; Final Rule, 68 Fed. Reg. 36,675 – 36,712 (June 18, 2003) (to be codified at 21 C.F.R. pt. 314). These new regulations were promulgated to prevent precisely the type of abuse that petitioners engaged in here. By these

new amendments, the FDA reiterated and clarified the provisions governing patent listing to make it more difficult for NDA-holders to abuse the Act by improperly listing irrelevant patents in the Orange Book and subsequently asserting them under § 271(e)(2) to prevent ANDA approval. The amended regulations make more explicit the pre-existing requirement that only patents that claim an approved use of a drug may be listed in the Orange Book. *See* 21 C.F.R. § 314.53(b) (effective August 18, 2003). Thus, the petition presents no important federal question. *See* SUP. CT. R. 10(c). The more stringent patent listing and filing requirements should prevent the issue at bar from reoccurring without any need for action by this Court. Accordingly, this case does not warrant further review by the Court and the petition should be denied.

I. THE FEDERAL CIRCUIT'S CONTROLLING INTERPRETATION OF § 271(e)(2) IS CORRECT

A. The *Warner-Lambert* Court Properly Construed The Language Of § 271(e)(2) Within The Context Of The Statutory Scheme As A Whole.

Seizing on the *Allergan* panel's criticism of the *Warner-Lambert* decision, petitioners contend that the *Warner-Lambert* court improperly allowed policy considerations, rather than the plain language of the statute, to dictate its construction of § 271(e)(2). That is not the case. The *Warner-Lambert* court expressly noted that "the starting point for every case involving construction of a statute is the language itself." App., *infra*, 9a. Implementing that rule, the court proceeded to interpret § 271(e)(2) by addressing the precise terms of the statute in the context of the Act as a whole, recognizing that 21 U.S.C. § 355(j), which governs the ANDA approval process, is expressly incorporated into 35 U.S.C. § 271(e)(2), the statutory basis for this action. *See Owasso Indep. School Dist. v. Falvo*, 534 U.S. 426, 434 (2002) (citing *Davis v. Michigan Dept. of Treasury,*

489 U.S. 803, 809 (1989)) ("It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.").

The crux of the *Warner-Lambert* court's reasoning was that:

> [B]ecause an ANDA may not seek approval for an unapproved or off-label use of a drug under 21 U.S.C. § 355(j)(2)(A)(i), it necessarily follows that 35 U.S.C. 271(e)(2)(A) does not apply to a use patent claiming only such a use. The statute recites "a drug . . . the use of which is claimed" (emphasis added), not "a drug . . . a use of which is claimed," or "a drug . . . any use of which is claimed," or "a drug having a use which is claimed." The FDA does not grant across-the-board approval to market a drug. Rather, it grants approval to make, use, and sell a drug for a specific purpose for which that drug has been demonstrated to be safe and efficacious. Read in the context of the Act, of which the provision now codified at 35 U.S.C. § 271(e) was just a part, it is clear that the phrase "the use" in § 271(e)(2)(A) refers to the use for which the FDA has granted an NDA.

App., *infra*, 12a. Thus, after a careful review of the statutory language, the Federal Circuit held that § 271(e)(2) does not provide a cause of action for infringement of method-of-use patents that do not claim "the" use for which the ANDA seeks approval. App., *infra*, 25a.

Nevertheless, petitioners argue that the *Warner-Lambert* interpretation is wrong and the "plain language" construction of § 271(e)(2) that the concurring opinions in *Allergan* advocated is correct. (P. Br. at 21). But, as a practical matter,

the statutory language at issue cannot be "plain" in the manner petitioners advocate, as a prior panel of the Federal Circuit adopted a diametrically opposed construction. *See Chickasaw Nation v. United States*, 534 U.S. 84, 90 (2001) (A statute is ambiguous if it is "capable of being understood in two or more possible senses or ways."). Under these circumstances, the statute should be read "in the manner that effectuates rather than frustrates the major purpose of the legislative draftsmen." *See Shapiro v. United States*, 335 U.S. 1, 31 (1948).

Appropriately, the *Warner-Lambert* court considered the legislative history and the stated purposes of the Act in construing the disputed language of § 271(e)(2). *See McDonald v. Santa Fe Trail Transp. Co.*, 427 U.S. 273, 287 (1976) ("whatever ambiguity there may be in the language of [the statute] is clarified by an examination of the legislative history . . ."); *Tidewater Oil Co. v. United States*, 409 U.S. 151, 157 (1972) ("while the clear meaning of statutory language is not to be ignored, 'words are inexact tools at best,' and hence it is essential that we place the words of a statute in their proper context by resort to the legislative history.") (internal citations omitted). Moreover, although the *Warner-Lambert* court's construction of § 271(e)(2) was not "policy driven" as petitioners suggest, it was entirely appropriate for the court to consider the underlying Congressional goals and policies in interpreting the statute. *See Johnson v. United States*, 529 U.S. 694, 710 n.10 (2000) (the Court "[has] never treated the text as such a jealous guide and ha[s] traditionally sought to construe a statute so as to reach results consistent with [] 'its object and policy'.") (internal citations omitted).

As explained, *supra* at 10, Judge Schall reviewed the language of § 271(e)(2) in isolation and without reference to the statutory scheme as a whole. Such approach to statutory construction is improper. As the Court stated in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000):

"[T]he words of a statute must be read in their context and with a view to their place in the overall statutory scheme. A court must therefore interpret the statute as a symmetrical and coherent regulatory scheme and fit, if possible, all parts into an harmonious whole." (internal quotation marks and citations omitted). Indeed, the Court has explicitly recognized that the provisions of the Hatch-Waxman Act should be interpreted by reference to the Act "taken as a whole." *Eli Lilly & Co. v. Medtronic, Inc.* 496 U.S. 661, 669 (1990). The *Allergan* panel disregarded this fundamental precept of statutory construction to arrive at petitioners' flawed construction which, if adopted, would frustrate the very purpose of the Act.

B. Other Sections Of The Act, The Legislative History And The FDA Regulations. Confirm The Federal Circuit's Controlling Interpretation That § 271(e)(2) Applies Only To Controlling Use Patents.

To be read consistently in the context of the Act as a whole, § 271(e)(2) must be interpreted to apply to controlling use patents only. Other provisions of the Act and its implementing regulations mandate that: (i) only patents which claim an approved use of a listed drug be listed in the Orange Book, and (ii) the certification provision does not apply to patents that do not claim a use for which ANDA approval is sought. Furthermore, the injunctive remedy for infringement under § 271(e)(2), if applied to a patent which does not claim the use for which an ANDA seeks approval, is inconsistent with the purposes of the Act and with general principles of patent law. *See* 35 U.S.C. § 271(e)(4)(A).

1. The Patent Listing Provision.

The listing provision, 21 U.S.C. § 355(b)(1), allows the NDA applicant to give notice regarding all of its *relevant* patents, by requiring that it file "the patent number and expiration date of any patent which claims the drug . . . or any patent which claims a method of using such drug and *with respect to which a claim of patent infringement could reasonably be asserted* . . ." *Id.* (emphasis added). Interpreted against the statutory scheme as a whole, the only patents with respect to which a claim of patent infringement could *reasonably* be asserted in the ANDA context are patents which claim the use for which an ANDA seeks approval which, by definition, is an approved use. The FDA implementing regulation makes unmistakably clear that only controlling use patents may be listed in the Orange Book:

> For patents that claim a method-of-use, the applicant shall submit information only on those patents that claim indications or other conditions of use *of a pending or approved application.*

21 C.F.R. § 314.53(b) (emphasis added). As the regulatory language makes clear, the "indications" or "conditions of use" must be found in a "pending or approved application." Since petitioners never filed an NDA for the use of brimonidine for neuroprotection, that specific use is not an indication or condition of use "of a pending or approved application." Therefore, petitioners' neuroprotection patents should not have been listed in the Orange Book and, as the *Warner-Lambert* court recognized, such patents cannot provide a basis for suit under § 271(e)(2).[7]

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7. The plaintiff-NDA–holder in *Warner-Lambert* conceded that its neurodegenerative method-of-use patent, which does not claim an approved use of the drug at issue, was improperly listed in the Orange Book and withdrew the listing the day after the Federal Circuit's decision was announced. *See Torpharm, Inc. v. Thompson*, 260 F. Supp.2d 69, 76 (D.D.C. 2003).

2. The Patent Certification Provision.

The patent certification provision requires certification for "each patent . . . *which claims a use for such listed drug for which the applicant is seeking approval.*" 21 U.S.C. § 355(j)(2)(A)(vii). Petitioners rely on Judge Schall's parsing of the language of this provision to argue that the highlighted language means that an ANDA applicant must certify to any patent which claims any use for the listed drug. (P. Br. at 26). But, as the *Warner-Lambert* court noted, this argument is unconvincing because "one does not obtain across-the-board approval to market a drug. Instead, one obtains approval to market a drug for a specific use for which the drug has been demonstrated to be safe and effective." App., *infra*, 25a. Closely examining the language of § 355(j)(2)(A)(vii) the court held that the phrase "use for such listed drug" was the antecedent for the phrase "for which the applicant is seeking approval." Thus, this section requires certification only for patents which claim the use for such listed drug for which the ANDA seeks approval.

Contrary to petitioners' arguments (P. Br. at 28-29), the legislative history regarding certification requirements supports the controlling Federal Circuit interpretation of the Act to the letter. Congress specified the only patents that require certifications as "product patents which claim the listed drug and all use patents which claim an indication for the drug for which the applicant is seeking approval (herein after described as a controlling use patent)." H.R. Rep. No. 98-857, pt. 1, at 22, *reprinted in* 1984 U.S.C.C.A.N. 2647, 2655. Congress expressly stated that "the committee intends that the applicant make the appropriate certification for each product and controlling use patent." *Id.* Recognizing that in some instances multiple certifications may be required for

product or controlling use patents, Congress gave examples of how certification was to work in practice:

> . . . [I]f there are indications which are claimed by any use patent and for which the applicant is *not* seeking approval, then an ANDA must state that the applicant is not seeking approval for those indications which are claimed by such use patent. For example, the listed drug may be approved for two indications. If the applicant is seeking approval only for Indication No. 1, and not Indication No. 2 because it is protected by a use patent, then the applicant must make the appropriate certification and a statement explaining that it is not seeking approval for Indication No. 2.

Id. Petitioners argue that this example means that even the patent covering Indication No. 2 must be certified to. But this argument must fail because that patent does not claim the use for which the ANDA seeks approval (*i.e.*, it is not a controlling use patent). (P. Br. at 29). Thus, the "appropriate certification" in the example refers only to indication number 1, the use for which the ANDA seeks approval.[8] By this example, it is clear that Congress anticipated an ANDA obtaining FDA approval even where another approved and patented use exists. Thus, petitioners' argument that it was Congress's "careful decision" to forestall approval of a generic drug for one use while a patent exists on another use rings hollow. (P. Br. at 18-19).

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8. Here, since brimonidine is approved for only one indication (lowering IOP), the particular example in the legislative history is not directly applicable to the present facts. Further, because petitioners' patents do not cover a use for which respondents' ANDA sought approval, a certification was not required, but as the district court noted, because the petitioners' patents were listed in the Orange Book respondents were forced to certify as practical matter. Pet. App. n.9 62a.

Further support that the certification requirement applies only to controlling use patents is the FDA regulation governing notice requirements for Paragraph IV certifications which indicates that the FDA's view of the statute is the same as the controlling Federal Circuit interpretation. *See* 21 C.F.R. § 314.95(a)(3) ("This paragraph does not apply to a use patent that claims no uses for which the applicant is seeking approval."). It is only upon receipt of the notice of certification that the 45 day period in which the NDA-holder may bring suit under § 271(e)(2) is triggered. Clearly, where neither certification nor notice is required for a patent which does not claim "a use for such listed drug for which the applicant is seeking approval," such patent cannot support a suit under § 271(e)(2).[9]

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9. The statutory language of § 271(e)(2) is both silent and ambiguous. As petitioners and Judge Linn note, the statute is silent on whether the predicate "use . . . claimed in a patent" must be an FDA-approved use. Moreover, the statute is ambiguous, as evidenced by the two opposing interpretations reached by the *Allergan* and *Warner-Lambert* panels of the Federal Circuit. However, if the statute "is silent or ambiguous with respect to the specific issue," "the court must sustain an agency's interpretation if it is based on a permissible construction of the statute." *Barnhart v. Walton,* 535 U.S. 212, 218 (2002), (*quoting Chevron, U.S.A., Inc. v. Nat'l Res. Def. Council, Inc.*, 467 U.S. 837, 843-44 (1988)).

C. Petitioners Are Not Entitled To Expand Their Patent Rights On Method-Of-Use Patents Through § 271(e)(2).

1. The Remedy For Infringement Under § 271(e)(2) Is Inappropriate To Address Infringement Of A Method-Of-Use Patent That Claims Only An Unapproved Use.

The remedy for infringement under § 271(e)(2) mandates an order preventing FDA approval of the ANDA for the entire unexpired term of the infringed patent. 35 U.S.C. § 271(e)(4)(A).[10] Therefore, a finding of infringement under § 271(e)(2) would bar *all* uses of brimonidine, including its FDA-approved, non-infringing use. Thus, the remedy petitioners seek in these circumstances is radically inconsistent with conventional patent law, where the appropriate remedy for inducement is a narrowly tailored injunction to prevent only the infringing activity. *See Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 775 (Fed. Cir. 1993). Even if respondents were to engage in inducing activity after ANDA approval, when petitioners could properly bring suit for inducement under § 271(b), respondents could be enjoined only from continuing the inducing activity, not from marketing their generic drug for its unpatented, approved use. *Id.*

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10. This remedy is appropriate only for infringement of a controlling use patent where the ANDA seeks approval for the patented use, because any sale of the generic drug for its approved use would inevitably result in infringement.

2. Petitioners' Interpretation Of § 271(e)(2) Improperly Equates Method-Of-Use Patents With Product Patents.

There is no basis under the Act to expand petitioners' patent rights on their off-label method-of-use patents to provide them a remedy they would not otherwise be entitled to under the patent laws. Petitioners do not hold an NDA for the patented purported new use of the drug and are therefore not entitled to benefits under the Act. However, petitioners are still entitled to their full panoply of rights under the patent laws. Rather than "destroy[ing] patent protections" for off-label use patents, as petitioners claim (P. Br. at 13), the decision below merely accords with basic patent law that a method of use patent "does not give rights equivalent to a product patent." *Chisum on Patents*, Vol. 1, § 1.03[8][c] at 1-294 (2003). Rather, "[t]he patentee's rights are confined to the particular [claimed] use of the product . . . Further, the patentee cannot directly control the manufacture and sale of product." *Id.*

The patentee can of course enforce a method-of-use patent after the FDA approves a particular drug, if a generic manufacturer engages in inducing activity and if, as a result of that activity, the patent is infringed. But, the patentee cannot use the limited protection provided by such a patent to prevent FDA from approving a generic drug for a non-infringing use. Indeed, if petitioners' position were adopted, they would retain the exclusive rights to all uses of this unpatented drug, including its only FDA-approved use —a use the Patent Office *explicitly* determined that petitioners could not patent.

3. Petitioners' Interpretation Of The Act Would Frustrate One of The Purposes Of The Act.

Petitioners' reading of § 271(e)(2) invites abuse. Indeed, under that interpretation, an NDA-holder could strangle generic competition by:

> regularly filing a new patent application claiming a narrow method of use not covered by its NDA. It would then be able to use § 271(e)(2)(A) as a sword against any competitor's ANDA seeking approval to market an off-patent drug for an approved use not covered by the patent. Generic manufacturers would effectively be barred altogether from entering the market. That would certainly not advance the purpose of making available "more low cost generic drugs," and was not what Congress intended.

App., *infra*, 17a. Petitioners' proliferation of narrow method-of-use patents on the same alleged invention and their successive infringement suits against respondents represent just such an anticompetitive scheme to prevent or delay FDA approval of generic versions of brimonidine to prolong petitioners' market exclusivity for that drug.[11] Thus, petitioners' interpretation would defeat the purpose of the Act and deprive the public of low cost generic drugs for unpatented FDA-approved uses.

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11. This case vividly illustrates the potential for abuse. After the district court granted summary judgment in this case, petitioners brought a second suit under § 271(e)(2) on a newly issued patent on the same "invention," *i.e.*, the neuroprotective use of brimonidine (a continuation of the patents-in-suit here). As a result, approval of respondents' ANDA was stayed for a second time. The district court again granted summary judgment relying heavily on the newly-published *Warner-Lambert* decision. *Alcon Labs., Inc. v. Allergan, Inc.*, 256 F. Supp.2d 1080 (C.D. Cal. 2003).

Therefore, since the FDA interpretation of the Act in promulgating regulations is entitled to deference, its interpretation of § 271(e)(2), as expressed in those regulations, commands the same deference. As explained *supra*, the patent listing regulation at 21 C.F.R. § 314.53(b), and the regulation governing notice of certification at 21 C.F.R. § 314.95(a)(3), both confirm the Federal Circuit's controlling interpretation that therefore merits the Court's deference.

II. THERE IS NO CONFLICT OR LACK OF CLARITY IN THE LOWER COURT TO MERIT THE COURT'S REVIEW

A. There Is No Lack Of Clarity In The Federal Circuit On The Interpretation Of § 271(e)(2).

The *Allergan* court below recognized that *Warner-Lambert* is the controlling Federal Circuit authority on the issue at bar and properly followed that established precedent in affirming this case, *per curiam*. Pet. App. 13a.

That the *Allergan* panel members voiced their criticisms of the *Warner-Lambert* decision in two concurring opinions is of no moment, because those concurrences have no precedential value. Furthermore, no obvious conflict remains within the court. The rehearing petition was heard by the full Federal Circuit court *en banc* and no judge, including any of the three judges from the *Allergan* panel, published a dissent from the order denying the rehearing *en banc*. *See Lough v. Brunswick*, 103 F.3d 1517 (Fed. Cir. 1997) (opinions dissenting from the Order denying rehearing *en banc* published by J. Newman, J. Michel and J. Rader).

Thus, because there is no conflict of authority within the Federal Circuit, there is no reason for the Court to review this case. *See* SUP. CT. R. 10(a).

III. THE COURT'S REVIEW IS UNNECESSARY BECAUSE THE SIGNIFICANCE OF THE FEDERAL QUESTION PRESENTED IS DIMINISHED BY THE NEW FDA IMPLEMENTING REGULATIONS

A. Recent Amendments To Regulations Governing Orange Book Listings Make It Unmistakably Clear That Patents Claiming Off-label Uses May Not Be Listed.

After the case was decided below, FDA promulgated new rules clarifying its interpretation of the statute, which in these circumstances is entitled to the Court's deference. *See Chevron U.S.A., Inc. v. Nat'l Res. Def. Council, Inc.*, 467 U.S. 837, 843-44 (1988). Amendments to the regulations governing patent listing and the 30-month stay provisions were made to counter abuse of these provisions by NDA-holders seeking to improperly extend their market exclusivity. *See* 68 Fed. Reg. 36,675, 36,688 (June 18, 2003). The new regulations restate the law with respect to listing method-of-use patents in the Orange Book, and further support respondents' interpretation of § 271(e)(2), since only method-of-use patents that claim an approved use of a drug may be listed in the Orange Book. *See* 21 C.F.R. § 314.53(b) (effective August 18, 2003). Because only listed patents can support an infringement action under § 271(e)(2), it necessarily follows that this section does not apply to *any* patent that claims *any* use of a drug as petitioners urge.

The new 21 C.F.R. § 314.53(b), as amended, is explicit in providing that only patents covering an approved use may be listed in the Orange book:

> For patents that claim a method of use, the applicant shall submit information only on those

> patents that claim indications or other conditions of use that are described in the pending or approved application. *The applicant shall separately identify each pending or approved method of use and related patent claim.* For approved applications, the applicant submitting the method-of-use patent *shall identify with specificity the section of the approved labeling that corresponds to the method of use claimed by the patent submitted.*

68 Fed. Reg. 36,675, 36,704 (June 18, 2003) (to be codified at 21 C.F.R. § 314.53(b)) (emphasis added). The new regulations have very specific reporting requirements and require that the patentee submit patent information accompanied by a sworn declaration on a special declaration form, *e.g.* FDA Form 3542.[12] *See id.* at 36,705 (to be codified at 21 C.F.R. § 314.53(c)). This declaration form requires that information is submitted "for each method of use claim referenced" and requires responses to the following questions:

> 4.1 Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement?
>
> 4.2 Claim Number (as listed in the patent)
>
> Does the patent claim referenced in 4.2 claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement?
>
> 4.2a If the answer to 4.2 is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product. (Submit indication

12. *Available at* http://forms.psc.gov/forms/FDA/Fda-3542a.pdf

> or method of use information as identified specifically in the proposed labeling.)

See FDA Form 3542. The NDA-holder must verify that the statements on Form 3542 are true under penalty of perjury and the threat that a "willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001." *Id.*

B. The Court's Review Is Unnecessary Where The Issue Has Little Significance Beyond The Instant Parties.

Accordingly, since the new patent listing requirements for method-of-use patents are so clear, it is unlikely that in the future, an NDA-holder will improperly list patents that do not claim approved uses of listed drugs in the Orange Book, as petitioners did here. It follows, that if only method-of-use patents which claim approved uses of listed drugs will be listed in the Orange Book, then future suits under § 271(e)(2) will necessarily be brought only on patents that claim approved uses of listed drugs.[13]

Because the facts of this case should not recur in the future, the question presented in petitioners' writ is not an important federal question of major significance to the pharmaceutical industry or to the public. Therefore, this issue, which has few if any ramifications beyond the instant case, does not satisfy any of the criteria for the exercise of this Court's discretionary jurisdiction. *See Bartlett v. Stephenson*, 535 U.S. 1301, 1304 (2002). Thus, it is respectfully submitted that the Court should deny the petition.

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13. Even if an NDA-holder were to violate the new listing regulations and list a use patent that does not claim an approved use of a drug, any infringement claim brought under § 271(e)(2) for that patent would be summarily dismissed under *Warner-Lambert*.

CONCLUSION

For the foregoing reasons, the petition for a writ of *certiorari* should be denied.

Respectfully submitted,

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APPENDIX — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT IN *WARNER-LAMBERT COMPANY v. APOTEX CORP., et al.* DATED JANUARY 16, 2003

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 02-1073

WARNER-LAMBERT COMPANY,

Plaintiff-Appellant,

v.

APOTEX CORP., Apotex, Inc., and Torpharm, Inc.,

Defendants-Appellees.

Jan. 16, 2003

Before *MICHEL*, Circuit Judge, *PLAGER*, Senior Circuit Judge, and *LOURIE*, Circuit Judge.

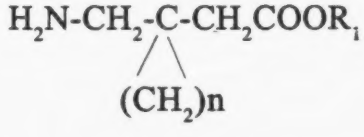
LOURIE, Circuit Judge.

Warner-Lambert Company appeals from the final order of the United States District Court for the Northern District of Illinois, granting summary judgment of noninfringement for Apotex Corp., Apotex Inc., and TorPharm, Inc. (collectively "Apotex"). *Warner-Lambert Co. v. Apotex Corp.*, No. 98 C 4293, 2001 U.S. Dist. LEXIS 14592, 2001

WL 1104618 (N.D.Ill. Sept.14, 2001). Because we hold that Apotex was entitled to judgment as a matter of law, we affirm.

BACKGROUND

Warner-Lambert is the assignee of U.S. Patent 5,084,479, entitled "Novel Methods for Treating Neurodegenerative Diseases." The '479 patent (the "neurodegenerative method patent") discloses and claims the use of certain cyclic amino acid compounds, as well as salts and esters derived from them, for the treatment of neurodegenerative diseases such as stroke, Alzheimer's disease, Huntington's disease, amyotrophic lateral sclerosis ("ALS"), and Parkinson's disease. Claim 1, the only independent claim in the 2C479 patent, defines the invention as follows:

> 1. A method for treating neurodegenerative diseases which comprises administering a therapeutically effective amount of a compound of formula
>
> 
>
> wherein R1 is hydrogen or a lower alkyl and n is 4, 5, or 6 or a pharmaceutically acceptable salt thereof, in unit dosage form, to a mammal in need of said treatment.

'479 patent, col. 10, ll. 8-19. One of these cyclic amino acid compounds, 1-aminomethyl-1-cyclohexane acetic acid,

corresponding to the formula in claim 1 in which R1 is hydrogen and n is 5, is commonly known as "gabapentin." Gabapentin is the subject of the present action.

Warner-Lambert is also the assignee of expired U.S. Patent 4,024,175, expired U.S. Patent 4,087,544, and U.S. Patent 4,894,476. The '175 patent (the "product patent"), entitled "Cyclic Amino Acids," disclosed and claimed the actual compounds that are used in the methods claimed in the neurodegenerative method patent; claim 2 specifically claimed 1-aminomethyl-1-cyclohexane acetic acid (*i.e.*, gabapentin). The '544 patent (the "epilepsy method patent"), entitled "Treatment of Cranial Dysfunctions using Novel Cyclic Amino Acids," disclosed and claimed a method of treating certain forms of epilepsy, faintness attacks, hypokinesia, and cranial traumas using the cyclic amino acid compounds claimed in the product patent and used in the methods of the neurodegenerative method patent, again including gabapentin. The '476 patent (the "monohydrate patent"), entitled "Gabapentin Monohydrate and a Process for Producing the Same," claims a specific crystalline form of gabapentin monohydrate. Gabapentin monohydrate is a complex made up of gabapentin and water.

Warner-Lambert sells gabapentin under the trade name Neurontin®. In 1993, Warner-Lambert obtained approval of a New Drug Application ("NDA") from the United States Food and Drug Administration ("FDA") to market gabapentin for use in "adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy," one of the several indications claimed in the now-expired epilepsy method patent. Significantly, the FDA

has not approved gabapentin for any additional uses, let alone for the uses claimed in the 2C479 neurodegenerative method patent.

Apotex filed an Abbreviated New Drug Application ("ANDA") under the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585 (popularly known as the Hatch-Waxman Act, hereinafter "the Act"), at the FDA on April 17, 1998, seeking approval to market a generic formulation of gabapentin upon the expiration of Warner-Lambert's epilepsy method patent on January 16, 2000. As mandated by 21 U.S.C. § 355(j)(2)(A)(i), Apotex sought approval to market gabapentin only for the same indication for which Warner-Lambert's Neurontin® was approved, *i.e.*, for "adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy." Along with the bioavailability/bioequivalence test data required to be included in its ANDA, Apotex filed a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV certification"), declaring that its proposed manufacture, use, and sale of gabapentin would not infringe either the monohydrate patent or the neurodegenerative method patent. According to Apotex, its formulation would be anhydrous (*i.e.*, would not contain water), and would accordingly be outside the scope of the monohydrate patent. Moreover, Apotex declared that its "pharmaceutical product's labeling does not include any indication for use in the treatment of either neurodegenerative or neurogenerative diseases." Because all of the claims of the neurodegenerative method patent "are directed to a use of gabapentin in the treatment of neurodegenerative diseases," Apotex argued, the manufacture, use, or sale of its gabapentin products would not infringe the neurodegenerative method patent.

Appendix

Under 21 U.S.C. § 355(j)(2)(B)(i), an ANDA applicant who files a paragraph IV certification is required to include in its application a statement that it will give notice of that filing to the owner of the patent to which the certification pertains, § 355(j)(2)(B)(i)(I), and to the holder of the approved NDA for that drug, § 355(j)(2)(B)(i)(II). Pursuant to those provisions, Apotex notified Warner-Lambert that it had filed the ANDA and paragraph IV certification. Also, as required by 21 U.S.C. § 355(j)(2)(B)(ii), Apotex provided in its notice letter a detailed statement of the factual and legal basis for its opinion of noninfringement of the neurodegenerative method patent. It explained that its "indicated use for its pharmaceutical product is partial seizure. The 2C479 neurodegenerative method patent does not claim a method of using gabapentin and its derivatives for partial seizure." Because the claims of the neurodegenerative method patent were limited to "a method of using gabapentin and its derivatives in the treatment of neurodegenerative diseases," and "partial seizure is not a neurodegenerative disease," Apotex argued that its gabapentin would "not fall within the scope of any of the claims of . . . the 2C479 patent."

Warner-Lambert commenced the present patent infringement action on July 14, 1998, alleging that Apotex's submission of its ANDA was an act of infringement of the neurodegenerative method patent under 35 U.S.C. § 271(e)(2)(A).[1] Although the FDA had not approved the use of

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1. Warner-Lambert also included a claim under the monohydrate patent. The district court granted summary judgment of noninfringement with respect to that patent on March 2, 2001. *Warner-Lambert Co. v. Apotex Corp.*, No. 98 C 4293, Doc. No. 67 (N.D.Ill. Mar. 2, 2001). The propriety of summary judgment with respect to that patent is not an issue raised by Warner-Lambert in this appeal.

gabapentin for any of the indications claimed in the neurodegenerative method patent, and 21 C.F.R. § 202.1(e)(4) forbids the promotion of unapproved uses by NDA or ANDA holders, Warner-Lambert argued that "patients will use the Apotex Defendants' gabapentin for all purposes for which Warner-Lambert's Neurontin® product has been and customarily is used, and doctors will prescribe the Apotex Defendants' gabapentin product for such uses, including the treatment of neurodegenerative diseases."

Apotex moved for summary judgment. Warner-Lambert opposed Apotex's motion, arguing that: (1) the FDA does not regulate the uses for which doctors prescribe drugs once they are approved, (2) "more than three-quarters of the prescriptions written by doctors for Warner-Lambert's Neurontin® are for indications other than epilepsy, including the treatment of neurodegenerative diseases," and (3) "doctors, managed care organizations, and other institutions commonly and routinely substitute generic drugs for all indications for which the brand name drug is used." Warner-Lambert's "Memorandum in Opposition to Apotex's Motion for Summary Judgment" at 20 (Dec. 10, 1998). Warner-Lambert further argued that "Apotex knows and expects that its generic gabapentin will be prescribed by doctors for all the same reasons they prescribe Neurontin," including "the treatment of . . . neurodegenerative diseases." *Id.* at 21. The district court denied Apotex's motion. *Warner-Lambert Co. v. Apotex Corp.*, No. 98 C 4293, 1999 U.S. Dist. LEXIS 6208, 1999 WL 259946 (N.D.Ill. Apr.8, 1999). At the close of discovery, however, Apotex again moved for summary judgment, and the district court granted that second motion. *Warner-Lambert Co. v. Apotex Corp.*, No. 98 C 4293,

2001 U.S. Dist. LEXIS 14592, 2001 WL 1104618 (N.D.Ill. Sept.14, 2001).[2]

Warner-Lambert now appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

"We review a district court's grant of summary judgment *de novo*, reapplying the standard used by the district court." *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 149 F.3d 1309, 1315, 47 USPQ2d 1272, 1275 (Fed.Cir.1998). Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). "The evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986).

A. *Infringement under 35 U.S.C. § 271(e)(2)*

The principal statute at issue in the present case provides as follows:

> It shall be an act of infringement to submit—
> (A) an application under section 505(j) of the

2. The second opinion mistakenly stated that "Plaintiff does not contend that defendants have violated 35 U.S.C. § 271(e)(2)(A)." *Warner-Lambert*, 2001 WL 1104618, 2001 U.S. Dist. LEXIS 14592, at *6 n. 3. Not only did Warner-Lambert assert a claim under § 271(e)(2)(A) in its complaint, but the applicability of that statutory provision is also one of the central issues in this appeal.

> Federal Food, Drug, and Cosmetic Act [codified at *21 U.S.C. § 355(j)*; *i.e.*, an ANDA] ... for a drug claimed in a patent or the use of which is claimed in a patent, ... if the purpose of such submission is to obtain approval under such Act [*i.e.*, Title 21 of the United States Code] to engage in the commercial manufacture, use, or sale of a drug ... claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2) (2000).

The district court's opinion took for granted that our decision in *Bayer AG v. Elan Pharmaceutical Research Corp.*, 212 F.3d 1241, 1248-49, 54 USPQ2d 1711, 1715-16 (Fed.Cir.2000), foreclosed Warner-Lambert's claim of infringement under 35 U.S.C § 271(e)(2)(A). *Warner-Lambert*, 2001 WL 1104618, 2001 U.S. Dist. LEXIS 14592, at *6 n. 3. The court then discussed whether or not Apotex would, alternatively, induce infringement of the neurodegenerative method patent under 35 U.S.C. § 271(b). Although we agree with the district court that Warner-Lambert has no cause of action under 35 U.S.C. § 271(e)(2)(A), we will also address the question whether Warner-Lambert has presented a genuine issue of material fact with respect to the elements of an inducement claim under § 271(b).

The central issue in the present case is whether it is an act of infringement under 35 U.S.C. § 271(e)(2)(A) to submit an ANDA seeking approval to make, use, or sell a drug for an approved use if any other use of the drug is claimed in a

patent, or if it is only an act of infringement to submit an ANDA seeking approval to make, use, or sell a drug if the drug or the use *for which FDA approval is sought* is claimed in a patent. That issue presents a matter of first impression for this court. Although we have previously construed portions of 35 U.S.C. § 271(e)(2) in *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 42 USPQ2d 1257 (Fed.Cir.1997), and in *Bayer*, we have not yet had occasion to parse the specific statutory language at issue here. For the reasons stated below, we conclude that it is not an act of infringement to submit an ANDA for approval to market a drug for a use when neither the drug nor that use is covered by an existing patent, and the patent at issue is for a use not approved under the NDA.

Because statutory interpretation is a legal issue, we review the district court's interpretation without deference. *Waymark Corp. v. Porta Sys. Corp.*, 245 F.3d 1364, 1366, 58 USPQ2d 1456, 1458 (Fed.Cir.2001). "The starting point of every case involving construction of a statute is the language itself." *Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 756, 95 S.Ct. 1917, 44 L.Ed.2d 539 (1975). Moreover, we "give effect, if possible, to every clause and word of [the] statute." *United States v. Menasche*, 348 U.S. 528, 538-39, 75 S.Ct. 513, 99 L.Ed. 615 (1955) (citation omitted). When a statute does not define a given word or phrase, we presume that Congress intended the word or phrase to have its ordinary meaning. *Asgrow Seed Co. v. Winterboer*, 513 U.S. 179, 187, 115 S.Ct. 788, 130 L.Ed.2d 682 (1995). However, "[i]n expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy."

U.S. Nat'l Bank of Or. v. Indep. Ins. Agents of Am., Inc., 508 U.S. 439, 455, 113 S.Ct. 2173, 124 L.Ed.2d 402 (1993) (internal quotation marks omitted). "When interpreting a statute, the court will not look merely to a particular clause in which general words may be used, but will take in connection with it the whole statute (or statutes on the same subject) and the objects and policy of the law, as indicated by its various provisions, and give it such a construction as will carry into execution the will of the Legislature." *Kokoszka v. Belford*, 417 U.S. 642, 650, 94 S.Ct. 2431, 41 L.Ed.2d 374 (1974) (internal quotation marks omitted).

Warner-Lambert argues that the district court erred in interpreting § 271(e)(2). It asserts that, under that provision, a patent claiming a use of a drug is infringed by the filing of an ANDA irrespective of whether approval is sought to market the drug for the patented use. We disagree. Warner-Lambert quotes the "pertinent part" of 35 U.S.C. § 271(e)(2)(A) as follows:

> It shall be an act of infringement to submit . . . an application under [the ANDA provisions of the Hatch-Waxman] Act for a drug . . . the use of which is claimed in a patent before the expiration of such patent.

Warner-Lambert's abridged quotation suggests that the mere filing of an ANDA for a drug having a use claimed in a patent is an infringing act *per se*. Based on that reading, Warner-Lambert argues that Apotex's ANDA infringes the neurodegenerative method patent:

> Apotex submitted an ANDA seeking FDA approval "for a drug" (gabapentin) "the use of which is

> claimed in" the 2C479 patent in suit. Section 271(e)(2)(A) explicitly defines the filing of an ANDA in the face of such a patent as an act of infringement.

Warner-Lambert's interpretation is incorrect. It has eviscerated an important part of the statutory provision by conflating the first and second clauses of § 271(e)(2)(A) in its quotation; the phrase "before the expiration of such patent" cannot be read apart from the phrase "if the purpose of such submission is to obtain approval under such Act." Whether or not other portions of the statute may be unclear, *cf. Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 679, 110 S.Ct. 2683, 110 L.Ed.2d 605 (1990) ("No interpretation we have been able to imagine can transform § 271(e)(1) into an elegant piece of statutory draftsmanship."), it is abundantly clear that the statute does not make the filing of an ANDA prior to patent expiration an act of infringement unless the ANDA seeks approval to manufacture, use, or sell the drug prior to expiration of a patent *that would otherwise be infringed* by such manufacture, use, or sale, *apart from* the provisions of § 271(e)(2). Accordingly, to prevail in this case, where the relevant patents covering the drug and the indication for which approval is sought have both expired, the plaintiff must prove that the defendant's manufacture, use, or sale of the drug would nonetheless infringe the neurodegenerative method patent under a traditional infringement analysis. At the very least, to succeed in this appeal of the district court's grant of summary judgment, Warner-Lambert would have needed to demonstrate the existence of a genuine issue of material fact to support a traditional infringement claim, *i.e.*, that Apotex induced or will induce infringement of the neurodegenerative method patent.

As Apotex notes, because an ANDA may not seek approval for an unapproved or off-label use of a drug under 21 U.S.C. § 355(j)(2)(A)(i), it necessarily follows that 35 U.S.C. 271(e)(2)(A) does not apply to a use patent claiming only such a use. The statute recites "a drug . . . *the* use of which is claimed" (emphasis added), not "a drug . . . *a* use of which is claimed," or "a drug . . . *any* use of which is claimed," or "a drug *having a use* which is claimed." The FDA does not grant across-the-board approval to market a drug. Rather, it grants approval to make, use, and sell a drug for a specific purpose for which that drug has been demonstrated to be safe and efficacious. Read in the context of the Act, of which the provision now codified at 35 U.S.C. § 271(e) was just a part, it is clear that the phrase "the use" in § 271(e)(2)(A) refers to the use for which the FDA has granted an NDA. That is, as we indicated above, the only use for which an ANDA applicant can seek approval. While a physician may prescribe an approved drug for any use consistent with acceptable medical practice, an NDA, and hence an ANDA, only approves a use for which safety and efficacy have been proven.

It is also significant that Congress used the word "a" before "drug" and the word "the" before "use." The words "the use" require antecedent basis; thus, "the use" refers to a specific "use" rather than a previously undefined "use." *See, e.g., Freytag v. Comm'r*, 501 U.S. 868, 902, 111 S.Ct. 2631, 115 L.Ed.2d 764 (Scalia, J., concurring) (analyzing the definite article "the" as narrowing a class to specific "envisioned" members of the class); *Work v. United States*, 262 U.S. 200, 208, 43 S.Ct. 580, 67 L.Ed. 949 (1923); *Am. Bus Ass'n v. Slater*, 231 F.3d 1, 4-5 (D.C.Cir.2000)

("[I]t is a rule of law well established that the definite article 'the' particularizes the subject which it precedes. It is a word of limitation as opposed to the indefinite or generalizing force of 'a' or 'an.'" (citations omitted)). Thus, the statutory language "the use" is most reasonably interpreted to mean "the use listed in the ANDA." Congress could have been expected to use quite different language if it wanted to reach the opposite result.

The history of the Hatch-Waxman Act is well known, *see, e.g.*, *Eli Lilly*, 496 U.S. at 665-78, 110 S.Ct. 2683, and we will not attempt to provide an exhaustive treatment of it here. Nonetheless, a brief review of that history will shed some light on the proper interpretation of § 271(e)(2)(A). Under federal law at the time the Act was negotiated and signed into law, a patent "granted to the patentee, his heirs, or assigns, for the term of seventeen years . . . the right to exclude others from making, using, or selling the invention throughout the United States." 35 U.S.C. § 154. "Except as otherwise provided . . . , whoever without authority makes, uses, or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent." *Id.* § 271(a).[3]

As the Supreme Court wrote in *Eli Lilly*, the Act was designed to respond to two problems that the patent and pharmaceutical regulatory statutes were perceived to have led to by the 1980s. 496 U.S. at 669, 110 S.Ct. 2683. One of those problems arose from the fact that an inventor ordinarily

3. Pub.L. No. 103-465, Dec. 8, 1994, expanded the definition of infringement in § 271(a) to include offers to sell patented inventions and importation into the United States.

applies for patent protection for newly discovered drugs, or for methods for the use of new or existing drugs, well before securing regulatory approval, even though it generally cannot legally market such products or promote their use until it obtains that approval. Since the FDA generally took much longer to approve an NDA than the United States Patent and Trademark Office took to grant a patent, a manufacturer's patent term was substantially eroded by the time the patentee was able to derive any profit from the invention. *Id.*[4]

The second problem inhered in the need for a generic manufacturer to obtain its own NDA if it wanted to market a product.[5] A new NDA required the generic company to provide its own safety and efficacy data, which it was argued was a waste of resources. This need was complicated by the assumption, confirmed by this court's holding in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858, 221 USPQ 937 (Fed.Cir.1984), that the plain language of § 271(a) made the manufacture and testing (a use) of a patented product prior to the expiration of the patent an act of infringement, even if that manufacture or use was solely for the purpose of conducting tests and developing the

4. Pub.L. No. 103-465 also revised § 154 such that, except as otherwise provided, for patents granted on applications filed on or after June 8, 1995, "such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States." That revision does not affect the present discussion, as it did not attenuate the potential distortions of patent term resulting from regulatory approval periods.

5. A separate statute once existed for antibiotics (21 U.S.C. § 357).

necessary information to apply for regulatory approval later on. *Eli Lilly*, 496 U.S. at 670, 110 S.Ct. 2683. Because it took a substantial amount of time for a second or subsequent manufacturer to obtain data and secure regulatory approval, requiring those manufacturers to wait until after the expiration of the patent to begin testing and other pre-approval activities resulted in a *de facto* extension of the patent term. The Hatch-Waxman Act intended to deal with both of these issues, *i.e.*, to restore to innovators patent time lost during testing and regulatory approval, but to enable generic manufacturers to be ready to enter the market once patents expired. The latter no longer would have to prove the safety and efficacy of a drug that was already the object of an NDA; they would just have to prove bioequivalence.

Section 201 of the Act, codified at 35 U.S.C. § 156, accordingly provided for patent term extension for products "subject to a regulatory review period before its commercial marketing or use," if "the permission for the commercial marketing or use of the product after such regulatory review period [was] the first permitted commercial marketing or use of the product." *Id.* at 676, 110 S.Ct. 2683 (quoting 35 U.S.C. § 156(a)).

Section 202 of the Hatch-Waxman Act added to 35 U.S.C. § 271 a new subsection, (e)(1), on the other hand, that provided that "it shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." *Id.* Section 271(e)(1) thus partially eliminated the second problem, *i.e.*, the *de facto*

unintended extension of the patent term, and enabled generic manufacturers to test and seek approval to market during the patent term. To further the overall goals of the Act, § 101 also amended § 505 of the Federal Food, Drug, and Cosmetic Act ("FDCA"), codified at 21 U.S.C. § 355, to authorize the filing and approval of ANDAs. *Id.* Included in the ANDA provisions was a mechanism to facilitate the adjudication of claims of infringement of patents relating to the innovator's drugs. That mechanism included, *inter alia*, provision for patentees and NDA holders to list patents that claim the approved drug or the approved use of the drug, 21 U.S.C. § 355(b)(1); and provision for ANDA applicants to "certify": (I) that no such patent information is listed, or, if such information is listed, then, for each listed patent, (II) that it has expired, (III) that it will expire prior to the ANDA applicant's marketing of the drug, or (IV) that it is invalid or will not be infringed by the manufacture, use, or sale of the drug by the ANDA applicant, 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV). *Eli Lilly*, 496 U.S. at 676-77, 110 S.Ct. 2683. The ANDA provisions now codified at 35 U.S.C. § 271(e)(2)(A) also created an artificial act of infringement that consists of submitting an ANDA containing a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that a listed patent is invalid or that the manufacture, sale, or use of the proposed product would not infringe that patent. *Eli Lilly*, 496 U.S. at 678, 110 S.Ct. 2683.

The Hatch-Waxman Act was accordingly a compromise between two competing sets of interests: those of innovative drug manufacturers, who had seen their effective patent terms shortened by the testing and regulatory processes; and those of generic drug manufacturers, whose entry into the market upon expiration of the innovator's patents had been delayed

by similar regulatory requirements. The legislative history of the Act stated its ultimate purposes:

> The purpose of Title I of the Bill is to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962. . . .
>
> The purpose of Title II of the Bill is to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval. The incentive is the restoration of some of the time lost on patent life while the product is awaiting pre- market approval.

H.R.Rep. No. 98-857(I), at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647-48. In light of this history, as well as the legislative language itself, we cannot agree with Warner-Lambert that Congress intended it to be an act of infringement under 35 U.S.C. § 271(e)(2)(A) to submit an ANDA for a drug if just any use of that drug were claimed in a patent and the applicant sought approval of its ANDA prior to the expiration of that patent.

Warner-Lambert's proposed interpretation is inconsistent with both of the stated purposes of the Hatch-Waxman Act, and would confer substantial additional rights on pioneer drug patent owners that Congress quite clearly did not intend to confer. If Warner-Lambert's interpretation were correct, for example, an NDA holder would be able to maintain its exclusivity merely by regularly filing a new patent application claiming a narrow method of use not covered by its NDA.

It would then be able to use § 271(e)(2)(A) as a sword against any competitor's ANDA seeking approval to market an off-patent drug for an approved use not covered by the patent. Generic manufacturers would effectively be barred altogether from entering the market. That would certainly not advance the purpose of making available "more low cost generic drugs," and was not what Congress intended. Moreover, although Warner-Lambert argues that our affirming the district court's decision would be a disincentive for research and development by innovators, Congress explicitly stated that the incentive created by the Act was patent term restoration. There is no evidence that Congress intended to enable an innovator to extend its exclusivity merely by asserting patents on unapproved uses. Moreover, if an innovator has not made the investment to test and obtain approval of the new use, what investment is to be protected by creating an added incentive?

Other relevant portions of the legislative history support our interpretation. For example, House Report No. 98-857(I) states, in part:

> . . . [A]n ANDA must include a certification by the applicant regarding the status of certain patents applicable to the listed drug if the patent information has been submitted under section 505(b) or (c). With respect to all product patents which claim the listed drug and all use patents which claim an indication for the drug for which the applicant *is seeking approval* (hereafter described as a *controlling* use patent), the applicant must certify, in his opinion and to the best of his knowledge, as to one of four circumstances.
>
> . . .

Appendix

> If appropriate, the applicant may certify that one or more of the product or *controlling* use patents provided have expired. . . . [A]n applicant may certify if applicable that one or more of the product or *controlling* use patents are invalid or will not be infringed.
>
> The committee recognizes that in some instances an applicant will have to make multiple certifications with respect to product or controlling use patents. For example, if the product patent has expired and a valid *controlling* use patent will not expire for three years, then the applicant must certify that one patent has expired and the other will expire in three years. The committee intends that the applicant make the appropriate certification for each product and *controlling* use patent.
>
> . . . [I]f there are indications which are claimed by any use patent and for which the applicant *is not seeking approval*, then an ANDA must state that the applicant is not seeking approval for those indications which are claimed by such use patent. For example, the listed drug may be approved for two indications. If the applicant is seeking approval only for Indication No. 1, and not Indication No. 2 *because it is protected by a use patent*, then the applicant must make the appropriate certification and a statement *explaining that it is not seeking approval for Indication No. 2.*

H.R.Rep. No. 98-857(I), at 22, 1984 U.S.C.C.A.N. at 2655 (emphasis added).

The quoted portion of the House Report demonstrates that Congress recognized that a single drug could have more than one indication and yet that the ANDA applicant could seek approval for less than all of those indications. Congress clearly contemplated that the FDA could grant approval of an NDA, and hence eventually an ANDA, seeking to market a drug for a single indication even when other indications were known or even approved. Moreover, and perhaps more importantly, Congress made it clear that the ANDA applicant need not certify with respect to every "use" patent that claims an indication for the drug. Rather, the applicant needs only to certify with respect to use patents that claim an indication *for which the applicant is seeking approval to market the drug. Id.*; *see also* H.R. Rep. No. 98-857(II), at 13 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2697 ("With respect to . . . all use patents which claim an indication for the drug for which the applicant is seeking approval, i.e., a controlling use patent, the applicant must certify. . . ."). And an ANDA applicant can only seek approval for a use approved in the underlying NDA.

The last example in the above-quoted portion of H.R. Rep. 98-857(I) describes a scenario very similar to the one at issue in the present case. Here, Apotex is seeking approval only for the indication of treating epilepsy, which corresponds to "Indication No. 1." It is not seeking approval for "Indication No. 2," *i.e.*, treatment of neurodegenerative diseases. Although Congress did not explicitly provide an example in which only Indication No. 1 is FDA-approved while only Indication No. 2 is still patented, the same conclusion applies *a fortiori* to that situation as to the provided example in which both indications are approved.

The applicant here is not only *stating* that it is not seeking approval for Indication No. 2, it is positively *forbidden* from obtaining such approval, unless it files its own NDA with full safety and efficacy data. Thus, according to H.R. Rep. 98-857(I), Apotex only needed to provide a statement explaining that it was not seeking approval for Indication No. 2. That it did. Although formally labeled as a "paragraph IV certification," we note that Apotex's statement with respect to the neurodegenerative method patent was effectively a statement of non-applicable use pursuant to 21 U.S.C. § 355(j)(2)(A)(viii).

Warner-Lambert argues that Apotex was required to certify under one of the subparagraphs of 21 U.S.C. § 355(j)(2)(A)(vii) with respect to the neurodegenerative method patent, because that patent was listed in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" publication (the "Orange Book"). That is incorrect. That provision and 21 U.S.C. § 355(j)(2)(A)(viii), which follows it, provide in pertinent part that:

> [An abbreviated application for a new drug shall contain—]
>
> (vii) a certification, in the opinion of the applicant and to the best of his knowledge, *with respect to each patent* which claims the listed drug referred to in clause (i) or *which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) . . . and*

> (viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

21 U.S.C. § 355(j)(2)(A)(vii)-(viii) (emphasis added). Thus, a certification need not be provided for a patent claiming a use for which the ANDA applicant is not seeking approval, *i.e.*, a use not covered by the NDA.

Warner-Lambert has not produced any authority that information regarding the neurodegenerative method patent was "required to be filed under subsection (b) or (c)"; indeed, the evidence of record suggests that it need not have been. The listing provision, 21 U.S.C. § 355(b), simply allows the innovator to give warning of all of its *relevant* patents, by requiring that it file with its application "the patent number and expiration date of any patent which claims the drug . . . or which claims a method of using such drug *and with respect to which a claim of patent infringement could reasonably be asserted.*" 21 U.S.C. § 355(b)(1) (emphasis added).[6]

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6. According to FDA regulations, only patents that claim an approved or pending use of a new drug can be submitted for listing in the Orange Book. The FDA promulgated 21 C.F.R. § 314.53 for submission of patent information by an NDA applicant for the Orange Book listing. For patents that claim a method of use, the FDA regulations state that "the applicant shall submit information only on those patents that claim indications or other conditions of use of

(Cont'd)

Of course, the mere listing of even a properly listed patent would not in itself entitle the patent owner to a judgment that that patent would be infringed by sale of the drug for an approved use. It simply provides the basis for a lawsuit that may be won or lost based on the general infringement provisions of the patent laws.

As noted above, the House Reports indicate that Congress intended to draw a distinction in the Act between those indications for which an ANDA applicant is seeking approval and those for which it is not when determining if certification is necessary. The applicant needs to certify only with respect to (a) product patents that claim the listed drug for which approval is sought, and (b) "controlling use patents," defined as patents that claim "an indication for the drug for which the applicant is seeking approval." Even when a listed drug is *approved* for more than one indication, Congress contemplated the possibility that there could be indications that are claimed by a use patent but for which the applicant is not seeking approval. There is no suggestion whatsoever in the statute or the legislative history that Congress intended that approval of a drug for a particular indication should be denied or even delayed by the existence of a patent that claims some other, unapproved indication of

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a pending or approved application." 21 C.F.R. § 314.53(b). Further, the FDA regulations expressly exclude from the certification requirements patents that claim no uses for which the applicant is seeking approval. 21 C.F.R. § 314.52(a)(3). The neurodegenerative method patent does not claim an indication in Warner-Lambert's currently approved NDA at issue in this case, and we have no information whether that patent claims a use in a pending application.

the drug. Although the issue is irrelevant to this case, we note that Apotex was likely required to, and did, certify under paragraph IV with respect to the monohydrate patent. We see no reason why the fact that Apotex *also* certified under paragraph IV with respect to the neurodegenerative method patent, perhaps in an overabundance of caution, should subject them to the Draconian penalty that Warner-Lambert seeks under 35 U.S.C. § 271(e)(4)(A) of having approval of their ANDA delayed until the expiration of the neurodegenerative method patent in the year 2010.

Warner-Lambert attempts in its reply brief to find significance in the fact that subsections (vii) and (viii) of 21 U.S.C. § 355(j)(2)(A) are connected with "the conjunctive 'and' rather than the disjunctive 'or,' " arguing that an ANDA applicant is required to file *both* a certification under subsection (vii) and a statement of inapplicable use under subsection (viii). That fact is irrelevant to our conclusion. As our analysis of the legislative history, *supra*, indicates, Congress contemplated the possibility that there could be more than one approved indication for a given drug, and that an ANDA applicant can seek approval to label and market the drug for fewer than all of those indications. In that situation, it would be necessary to certify under subsection (vii) with respect to a patent claiming an indication for which approval is sought, and to file a statement of inapplicable use under subsection (viii) with respect to the other indications. In a situation such as the one at issue in the present case, however, where the applicant is *not* seeking approval to market a drug for a use claimed in a patent, there is no need to file any certification at all under subsection (vii).

Warner-Lambert further argues that "[a] comparison of the language in subparts (vii) and (viii) confirms that the antecedent for the phrase 'for which the applicant is seeking approval' in subpart (vii) is 'drug' rather than 'use'. In contrast . . . subpart (viii) . . . does use the phrase 'a use for which the applicant is seeking approval,' and the phrase 'for which the applicant is seeking approval' obviously modifies 'use'." That argument is unconvincing. As we noted above, one does not obtain across-the-board approval to market a drug. Instead, one obtains approval to market a drug for a specific use for which the drug has been demonstrated to be safe and effective. Thus, the antecedent for the phrase "for which the applicant is seeking approval" in subpart (vii) is neither "drug" nor "use," but "use for such listed drug."

In summary, Warner-Lambert does not have a cause of action under § 271(e)(2)(A). Congress clearly intended to limit actions for infringement of method-of-use patents under § 271(e)(2)(A) to "controlling use patents," or patents that claim an approved use of a drug. An ANDA applicant, who necessarily "piggybacks" on the approved NDA of the innovator, can only apply to sell the approved drug, which, in this case, is no longer under patent, and to market it for the use for which the FDA has indicated that the drug is safe and efficacious, for which use the patent here has also expired. Apotex has neither submitted an application to sell a drug claimed in an extant patent, nor submitted an application to sell a drug the use of which is claimed in an extant patent. Both gabapentin and its only FDA-approved use are now off-patent.

Because Apotex is not submitting an application to sell a drug for treatment of neurodegenerative diseases, which is the only use covered by the patent involved in this case, we conclude that Apotex is entitled to summary judgment of noninfringement.

B. Infringement under 35 U.S.C. § 271(b)

Having concluded that 35 U.S.C. § 271(e)(2)(A) is inapplicable to the present case and that Warner-Lambert accordingly does not have a cause of action against Apotex under that statute, we might close this opinion here. However, since the issue has been decided by the district court and argued here, and since it may arise if Apotex's ANDA is approved, we will address the question whether Warner-Lambert has demonstrated the existence of a genuine issue of material fact with respect to inducement under 35 U.S.C. § 271(b).

As an initial matter, we note that there is no evidence in the record that Apotex has directly practiced or will ever practice any of the methods claimed in the neurodegenerative method patent, all of which are directed to a method for treating neurodegenerative diseases by administering gabapentin or another cyclic amino acid compound to a mammal.[7] Accordingly, Warner- Lambert has not established

7. That is hardly surprising—pharmaceutical companies do not generally treat diseases; rather, they sell drugs to wholesalers or pharmacists, who in turn sell the drugs to patients possessing prescriptions from physicians. Pharmaceutical companies also occasionally give samples of drugs to doctors and hospitals. In none

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that there is any genuine issue of material fact with regard to direct infringement by Apotex, and Warner-Lambert therefore has no cause of action for direct infringement under 35 U.S.C. § 271(a).

Warner-Lambert has asserted inducement of infringement under 35 U.S.C. § 271(b). Under § 271(b), "whoever actively induces infringement of a patent shall be liable as an infringer." To succeed on this theory, a plaintiff must prove that the defendants' "actions induced infringing acts and that [they] knew or should have known [their] actions would induce actual infringement." *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553, 16 USPQ2d 1587, 1594 (Fed.Cir.1990). However, that defendants have "knowledge of the acts alleged to constitute infringement" is not enough. *Id.* "[P]roof of actual intent to cause the acts which constitute the infringement is a necessary prerequisite to finding active inducement." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1529 (Fed.Cir.1990). "Inducement requires proof that the accused infringer knowingly aided and abetted another's direct infringement of the patent." *Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1306, 50 USPQ2d 1429, 1437 (Fed.Cir.1999). "While proof of intent is necessary, direct evidence is not required; rather, circumstantial evidence may suffice." *Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660, 668, 7 USPQ2d 1097, 1103 (Fed.Cir.1988).

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of these cases, however, does the company itself *treat* the disease. There can of course be exceptions to this rule, such as in-house testing to establish bioequivalence and bioavailability (which would in any event be noninfringing according to 35 U.S.C. § 271(e)(1)), but they are not relevant here.

Appendix

Warner-Lambert argues that the district court erred in requiring that, to be liable for inducement, Apotex had to have "known" that physicians were prescribing gabapentin for treatment of neurodegeneration. Warner-Lambert contends that the district court ignored the "should have known" standard. According to Warner-Lambert, by 1998, only about 22% of gabapentin sales were for treatment of epilepsy, the remaining 78% being prescribed for off-label uses, including the infringing use of treating neurodegenerative diseases. By October 1999, the percentage of uses other than for epilepsy treatment had risen to "more than 89%." In addition, Warner-Lambert argues that: (1) it is common knowledge to many in and out of the pharmaceutical field that physicians routinely prescribe approved drugs for purposes other than those listed on the drugs' labels; indeed, such off-label use is supported by both the FDA and the American Medical Association, (2) information regarding both on- and off-label prescriptions is readily available to the public from publications and databases to which most pharmaceutical companies subscribe, (3) "pharmacists and other drug dispensing organizations . . . commonly substitute generic drugs for name brand drugs wherever possible—unless specifically instructed otherwise by the physician writing the prescription," and, "in many states, substitution is mandatory," (4) Apotex expects to get an "A-B rating" for its gabapentin, which would allow physicians and pharmacists to substitute generic gabapentin for Neurontin® regardless of the indication for which it is to be used, and (5) Apotex should be assumed to have considered the market size and growth potential of gabapentin when it made the strategic decision to file an ANDA and enter the gabapentin market.

Whether or not these statements are true, and for the purposes of deciding whether or not summary judgment was proper we must assume they are, we have already observed that precedent holds that mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven. *Manville Sales*, 817 F.2d at 554. Thus, if a physician, without inducement by Apotex, prescribes a use of gabapentin in an infringing manner, Apotex's knowledge is legally irrelevant. In the absence of any evidence that Apotex has or will promote or encourage doctors to infringe the neurodegenerative method patent, there has been raised no genuine issue of material fact.

Warner-Lambert also argues that the court ignored its own earlier ruling that intent and knowledge must be assessed as of the date of hypothetical FDA approval, rather than at the time the decision was made to file the ANDA. According to that ruling, the relevant question would be whether Apotex would actively induce infringement when its ANDA is approved and it introduces generic gabapentin to the market, rather than whether Apotex had the intent to induce infringement at the time it filed its ANDA. Even if Warner-Lambert is correct, however, and if we assume that Apotex did not have knowledge of the potential for infringing use at the time it filed its ANDA, but that it does now as a result of this lawsuit, we have already held that mere knowledge alone of possible infringement by others is insufficient to prove inducement. In any event, the ANDA must be judged on its face for what an accused infringer seeks the FDA's approval to do. Section 271(e)(2) does not encompass "speculative" claims of infringement. The statute explicitly defines the act

of infringement as the filing of the ANDA. The infringement case is therefore limited to an analysis of whether what the generic drug maker is requesting authorization for in the ANDA would be an act of infringement if performed. Here, the request to make and sell a drug labeled with a permissible (non-infringing) use cannot reasonably be interpreted as an act of infringement (induced or otherwise) with respect to a patent on an unapproved use, as the ANDA does not induce anyone to perform the unapproved acts required to infringe. That a generic maker may someday induce someone to infringe can only be determined when that act occurs, and § 271(e)(2) was not designed to cover such future acts.

Moreover, according to Warner-Lambert's own data, only about 2.1% of the prescriptions written for gabapentin from August 1999 to July 2000 were for neurodegenerative diseases. Even viewing the evidence in the light most favorable to Warner-Lambert, and assuming that Apotex is "counting on" sales for off-label uses, it defies common sense to expect that Apotex will actively promote the sale of its approved gabapentin, in contravention of FDA regulations, for a use that (a) might infringe Warner-Lambert's patent and (b) constitutes such a small fraction of total sales.

Even if Warner-Lambert's estimate that 2.1% represents $50 million is correct,[8] it is an inescapable fact that the

8. It is not entirely clear what the basis is for Warner-Lambert's $50 million figure; 2.1% of Warner-Lambert's own $1.1 billion in Neurontin® sales in 2000 is only about $23 million, and there is no evidence of record to controvert Apotex's assertion that that market will shrink as a result of studies showing that gabapentin is ineffective for treatment of ALS and spinal muscular atrophy.

remaining 97.9% still represents more than 46 times that amount. Especially where a product has substantial noninfringing uses, intent to induce infringement cannot be inferred even when the defendant has actual knowledge that some users of its product may be infringing the patent. Where there are many uses for a product, as the record reflects to be true of gabapentin, and fewer than 1 in 46 sales of that product are for infringing uses, we are not in a position to infer or not infer intent on the part of Apotex without any direct evidence.

Warner-Lambert raises two other rather curious arguments in its briefs. First, it argues that the district court erred by applying principles regarding the law of inducement under 35 U.S.C. § 271(b) to actions brought under 35 U.S.C. § 271(e)(2)(A). Warner-Lambert asserts that "Section 271(e)(2)(A) states that the filing of an ANDA for a drug 'the use of which is claimed in a patent' is an act of infringement and mentions neither inducement nor any of the judicially developed intent factors that give rise to inducement." Therefore, Warner-Lambert argues, once it is established that prescriptions are being written for a patented use, the ANDA filing itself represents an act of infringement.

Warner-Lambert is mistaken. As we explained in *Glaxo*, 35 U.S.C. § 271(e)(2)(A) simply provides an "artificial" act of infringement that creates case-or-controversy jurisdiction to enable the resolution of an infringement dispute before the ANDA applicant has actually made or marketed the proposed product. 110 F.3d at 1569, 42 USPQ2d at 1263. Once jurisdiction is established, however, the substantive determination whether actual infringement or inducement

will take place is determined by traditional patent infringement analysis, just the same as it is in other infringement suits, including those in a non-ANDA context, the only difference being that the inquiries now are hypothetical because the allegedly infringing product has not yet been marketed. *Id.* (holding that the patentee still carries the burden to prove that the product a generic drug maker ultimately will put on the market would likely infringe the patent). "The plain language of [35 U.S.C. § 271(e)(2)(A)] does not alter a patentee's burden of proving infringement." *Id.* at 1567, 110 F.3d 1562, 42 USPQ2d at 1262. The proper inquiry under § 271(e)(2)(A) is "whether, if a particular drug *were* put on the market, it *would* infringe the relevant patent." *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1135, 36 USPQ2d 1641, 1646 (Fed.Cir.1995). In *Glaxo*, we also rejected the argument that an action brought under § 271(e)(2)(A) requires a unique type of infringement analysis in which the burden is shifted to the accused infringer to disprove infringement where the ANDA would permit sale of a composition that may include an infringing product. 110 F.3d at 1568, 42 USPQ2d at 1262. We held in that case that "a patentee seeking relief under § 271(e)(2) must prove by a preponderance of the evidence that what is to be sold will infringe. That burden is not shifted under § 271(e)(2)." *Id.*

Secondly, Warner-Lambert argues that the district court transplanted into § 271(e)(2)(A) principles "developed in a wholly inapposite non-ANDA context," and extrapolated from both § 271(b) and the holding in *Manville Sales* to formulate a more stringent standard and to impose a higher burden of proof than would have been encountered in an

infringement suit brought directly under § 271(b) rather than under § 271(e)(2)(A). Again, Warner-Lambert is mistaken. The district court did not transplant any alien principles into § 271(e)(2)(A); rather, the court concluded that Warner-Lambert's claim under § 271(e)(2)(A) was foreclosed, and then proceeded to address the question whether or not a genuine issue of material fact existed with regard to an inducement claim. *Warner-Lambert*, 2001 WL 1104618, 2001 U.S. Dist. LEXIS 14592, at *6.

We have considered Warner-Lambert's other arguments, including its argument that the court resolved several genuinely disputed issues of material fact adversely to Warner-Lambert, and find them unpersuasive.

CONCLUSION

The district court did not err in granting summary judgment of noninfringement in favor of Apotex. The court's decision to award judgment to Apotex is therefore

AFFIRMED.

Supreme Court, U.S.
FILED
OCT 2 4 2003
OFFICE OF THE CLERK

No. 03-443

IN THE
Supreme Court of the United States

ALLERGAN, INC. and ALLERGAN SALES, INC.,

Petitioners,

v.

ALCON LABORATORIES, INC., ALCON RESEARCH, LTD.,
ALCON UNIVERSAL, LTD.,
and BAUSCH & LOMB INCORPORATED,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION FOR RESPONDENT BAUSCH & LOMB INCORPORATED

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QUESTION PRESENTED

Whether the owner of a method of use patent can bring a preemptive law suit under 35 U.S.C. § 271(e)(2), where the alleged infringer has filed an Abbreviated New Drug Application seeking approval from the Food and Drug Administration to market a generic drug for a use that is not covered by the patent?

CORPORATE DISCLOSURE STATEMENT

Respondent Bausch & Lomb Incorporated has no parent corporation nor are there any publicly held companies that own 10 percent or more of the stock of respondent Bausch & Lomb Incorporated.

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OPINIONS BELOW

The decision of the district court granting respondent Alcon's motion for summary judgment was entered on May 8, 2002 and is reported at *Allergan, Inc. v. Alcon Labs., Inc.*, 200 F. Supp. 2d 1219 (C.D. Cal. 2002). The decision of the district court granting respondent Bausch & Lomb's ("B&L") motion for summary judgment was entered on June 4, 2002 and is unreported. The opinion of the Federal Circuit affirming the grant of summary judgment in favor of respondents Alcon and B&L was entered on March 28, 2003, and is reported at *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322 (Fed. Cir. 2003). The order of the Federal Circuit denying petitioner Allergan's request for rehearing *en banc* was entered on May 22, 2003 and is unreported.

STATEMENT OF THE CASE

The question "of exceptional importance" which petitioner Allergan seeks to have the Court review is not the subject of conflicting decisions by the Federal Circuit below. Nor is it a question that was decided by a "close" split of the full Federal Circuit sitting *en banc*. Rather, the issue was previously decided by a unanimous three-judge panel of the Federal Circuit in *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003), a decision for which further review was never sought. When the same issue arose in this case, a second three-judge panel of the Federal Circuit followed the holding of the *Warner-Lambert* panel, albeit reluctantly. When Allergan petitioned to have the question reheard by the full Federal Circuit sitting *en banc*, the Federal Circuit summarily declined.

\ At issue is whether the owner of a patent which covers a particular method of using a drug can bring a preemptive patent infringement law suit under 35 U.S.C. § 271(e)(2) against a generic drug manufacturer that files an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA"), where the ANDA seeks approval to market the drug for a method of use ***that is not covered by the patent***. Recognizing that to allow such a suit would lead to an absurd scenario in which a generic drug company would be precluded from selling to the consumer a public domain drug for a public domain use of that drug, the Federal Circuit quite understandably answered the question in the negative. As a result, research-based drug companies such as petitioner cannot seek ***preemptive*** relief under this narrow set of circumstances. Of course, all of the traditional remedies for patent infringement are still available to these patent holders, which provide more than enough incentive for them to research new uses of existing drugs.

A. The New Drug Application

Congress enacted the Hatch-Waxman Act in 1984 "to benefit makers of generic drugs, research-based pharmaceutical companies, and not incidentally the public." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997). One of the benefits to research-based pharmaceutical companies was the implementation of the New Drug Application ("NDA") system under which a period of marketing exclusivity would be granted to companies which conducted clinical studies to establish the safety and efficacy of a drug product – even if the drug product was in the public domain. Petitioner took advantage of this system to obtain a period of marketing exclusivity for a drug containing "brimonidine" as its active ingredient.

The chemical "brimonidine" was originally patented in 1975 by Pfizer as a drug useful for treating hypertension. The Pfizer patent expired in 1992. Brimonidine is, therefore, in the public domain. *Bonito Boats Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989) ("It is self-evident that on the expiration of a patent the monopoly created by it ceases to exist, and the right to make the thing formerly covered by the patent becomes public property."). As early as 1986, researchers published findings showing that, when applied topically to ocular tissue, brimonidine was effective in reducing intraocular pressure ("IOP") in rabbits, cats and monkeys. By 1995, brimonidine had been used to lower IOP in humans, and specifically for the treatment of "glaucomatous hypertension" in humans. Thus, the use of brimonidine to lower IOP in mammals, including humans having glaucoma and ocular hypertension, is in the public domain.

In 1995, petitioner filed an NDA with the FDA for approval to market an ophthalmic drug product containing brimonidine as its active ingredient. The FDA does not grant approvals to market a drug for any purpose; rather, the applicant must specify the use (or uses) for the drug and submit clinical data which demonstrates that the drug is effective for that use. Petitioner's NDA sought approval for one use of the brimonidine drug and one use only – "lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension." Petitioner submitted clinical and other data to the FDA establishing the safety and efficacy of the drug only for this use. In September 1996, the FDA approved petitioner's NDA for the *sole use* of lowering IOP.

The approval of petitioner's NDA entitled it to a five and a half year period of marketing exclusivity, even though

the use of brimonidine to lower IOP in patients with open-angle glaucoma or ocular hypertension was in the public domain. Petitioner's period of FDA-granted exclusivity expired on March 6, 2002.

B. Petitioner's Method of Use Patents and the Patent Listing Procedure

During this period of exclusivity, petitioner filed for and was granted two patents which are directed to a method of using brimonidine in mammals to achieve the effect of "neuroprotection." Petitioner uses the term "neuroprotection" to describe the direct treatment of the optic nerve to prevent glaucoma, as distinct from treatments which lower IOP. Thus, the claims of these patents (referred to hereinafter as "the neuroprotection patents") do not cover the use of brimonidine to lower IOP.

Under 21 U.S.C. § 355 (the section of the Food, Drug and Cosmetic Act pertaining to NDAs), the owner of an approved NDA is required to provide to the FDA the identity of patents which cover the approved drug product. According to the FDA regulations implementing 21 U.S.C. § 355, "[f]or patents that claim a method of use, the applicant shall submit information only on those patents that claim indications or other conditions of use of a pending or approved application." 21 C.F.R. § 314.53(b).[1] The submitted patents are published by the FDA in the "Orange Book." *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e).

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1. The FDA recently amended its regulations to make it even more clear that only patents which claim a method of use ***for which the drug has been approved*** should be listed. *See* discussion *infra* Part II.

After the neuroprotection patents issued, petitioner submitted them for listing with the FDA, despite the fact that they do not claim the use of brimonidine to lower IOP, the only use set forth in the NDA. Since the FDA does not check the substance of its listings, but merely acts in a clerical, ministerial capacity, the FDA listed these patents in its "Orange Book."

C. The Abbreviated New Drug Application

Another purpose of the Hatch-Waxman Act was "to enable new drugs to be marketed more cheaply and quickly." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). To this end, near the end of the period of exclusivity granted to the holder of an approved NDA, a competitor may file an ANDA to seek approval to market a generic version of the drug once the period of exclusivity expires. *See* 21 U.S.C. § 355(j)(5)(D)(ii). In October 2001, respondent B&L submitted an ANDA to the FDA seeking approval to market a generic version of petitioner's brimonidine product.

Unlike an NDA, an ANDA applicant is not required to submit human clinical studies to show that the drug is safe and effective for various uses for which the manufacturer seeks approval. An ANDA simply contains information which supports bioequivalence to the brand-name drug product, usually because it contains the same ingredients. *See* 21 U.S.C. §§ 355(j)(2)(A)(ii)(I), 355(j)(2)(A)(iii), 355(j)(2)(A)(iv). Since an ANDA does not contain human clinical data, by law, a generic drug cannot be approved for any use beyond the uses approved by the FDA in the brand-name's NDA. 21 U.S.C. § 355(j)(2)(A)(i).

Moreover, the labeling for the generic drug is required to be the same as the labeling for the brand-name drug. 21 U.S.C. § 355(j)(2)(A)(v). As a result, respondent B&L sought approval from the FDA to market and label its generic brimonidine product for one use and one use only – the public domain use of "lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension." Since the neuroprotective use claimed in petitioner's patents is different from the labeled use of lowering IOP, the neuroprotective use is referred to as an "off-label" use.

As part of its application, an ANDA applicant is required to submit a certification, with respect to each listed and unexpired patent "which claims a use for such listed drug for which the applicant is seeking approval . . . that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . ." 21 U.S.C. § 355(j)(2)(A)(vii). In respondent's view, there was no need to submit a certification with respect to petitioner's neuroprotection patents because neither patent claims the use for which respondent was seeking approval: the lowering of IOP. Nevertheless, out of an abundance of caution, and because petitioner had listed the neuroprotection patents with the FDA (improperly in respondent's view) and the FDA had published the patents in the Orange Book, respondent B&L filed a certification that those patents would not be infringed.

After respondent B&L notified the petitioner of its ANDA (such notification is required when an ANDA applicant files a certification that a patent will not be infringed), petitioner shortly thereafter filed suit against respondent B&L for patent infringement under 35 U.S.C. § 271(e)(2) (petitioner simultaneously filed suit against

respondent Alcon). By filing this suit, petitioner automatically triggered a provision of 21 U.S.C. § 355(j) which prevents the FDA from approving a generic product for 2½ years unless a judgment of noninfringement or invalidity is rendered prior to the expiration of that time. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I).

D. Petitioner's Infringement Claims

Title 35 of U.S.C. § 271(e)(2) provides that "[i]t shall be an act of infringement to submit –

> . . . an [ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."

Respondent B&L, as a manufacturer of brimonidine, will not itself use the drug for the alleged neuroprotection. B&L is also precluded from promoting brimonidine for neuroprotection. Under FDA law, drug manufacturers and sellers – including B&L – cannot legally promote any use of a drug except the one approved by the FDA. *See* 21 U.S.C. §§ 331, 332, 333, 334, 352.

Nevertheless, petitioner Allergan alleged in the district court that if respondent B&L were to obtain approval to bring its generic brimonidine drug product to the market, B&L would then ***actively induce*** doctors and patients to use that drug for the neuroprotective uses covered by petitioner's

patents. Thus, argued petitioner, B&L's filing of an ANDA for approval to market a drug containing brimonidine was an act of infringement under 35 U.S.C. § 271(e)(2).

Whether or not respondent B&L would seek to actively induce the infringement of petitioner's patents upon obtaining approval of its ANDA (which it would not do) is irrelevant to the issue that petitioner would have the Court review (whether section 271(e)(2) can ever be invoked with an off-label use patent). Nonetheless, in what is apparently a desperate effort to influence the Court by painting respondent B&L in a poor light, petitioner makes a number of factual misstatements that respondent B&L is compelled to correct.

In particular, B&L is not "fully aware . . . that . . . the vast majority of glaucoma patients are candidates for neuroprotective treatment, and that respondents' generic versions of brimonidine can and will be used for the unapproved neuroprotective use claimed in petitioner's patent." Petition at 8. Petitioner failed to produce any credible evidence that doctors are actually prescribing brimonidine for the so-called effect of neuroprotection, and B&L is certainly not aware of any such activity by doctors. The best that can be said is that research into the neuroprotective properties of brimonidine is ongoing, but no concrete evidence supports the conclusion that brimonidine achieves this effect in humans. Therefore, B&L does not "know" that its brimonidine product will be used, contrary to its labeling, for neuroprotection.

Furthermore, respondent B&L has not, as petitioner would have the Court believe, taken any steps to encourage the use of brimonidine for neuroprotection. Petitioner's "evidence" is that B&L sponsors a research website upon

which one can find an abstract about neuroprotection. What petitioner omits is that the website is owned by a University and operated completely independent of respondent B&L, and indeed the site contains a conspicuous statement that B&L is ***not involved*** in and does not make any representations about the content of the website. Furthermore, the abstract in question which can be found by searching the database on the site ***was authored by the petitioner.*** It strains credulity to suggest that B&L is actively inducing doctors to make neuroprotective use of brimonidine in humans rather than the use to lower IOP, because B&L simply provides a monetary donation to a University that independently monitors the published literature, stores it on a web-site database with thousands of already-published ophthalmic articles, such that, if the database is searched by a person looking for "brimonidine," the person can find among other articles an article written an published by petitioner Allergan, which would be found elsewhere by searching the web anyway.

REASONS FOR DENYING THE PETITION

Petitioner has presented no compelling reason for the Court to grant its petition. First, there is no conflict among the federal courts which requires resolution by this Court, and the issue raised by petitioner is not such an important question of federal law as to warrant review by this Court. In particular:

- The issue was decided by a unanimous three-judge panel of the Federal Circuit, and when invited to consider the case *en banc*, the Federal Circuit declined.

- Notwithstanding petitioner's farfetched arguments to the contrary, drug patent holders have not been stripped of all incentives as a result of the Federal Circuit's decision. While research-based drug companies such as petitioner may be precluded from bringing a preemptory action to automatically prevent entry into the market for all uses (including public domain uses) of a particular drug, there is no question that, on the very day that a generic drug enters the market, those companies can bring suit for induced infringement and move for a temporary restraining order and a preliminary injunction against the off-label uses – assuming they have the appropriate strong evidence of inducement to support this extreme relief.

Second, the petition should be denied because the Federal Circuit's interpretation of the statute is the correct one. The plain language of the statute, coupled with the statutory framework of the Hatch-Waxman Act, its legislative history, and public policy concerns, compel the conclusion reached by the Federal Circuit that section 271(e)(2) provides no cause of action for infringement of method patents that do not claim the method for which an ANDA applicant is seeking approval.

I. There Are No Conflicting Decisions Below Nor Exceptional Questions Of Law Which Would Warrant The Attention Of This Court

A. The Issue Raised By Petitioner Has Been Put To Rest By The Federal Circuit

Petitioner makes much out of the fact that the concurring opinions from the *Allergan* decision below criticized the Federal Circuit's decision in the *Warner-Lambert* case. The fact is, however, that the panel below followed the *Warner-Lambert* decision and thus created no conflict in the precedent. Not satisfied with this outcome, petitioner put the issue squarely before the entire Federal Circuit by petitioning for rehearing *en banc*. The Federal Circuit declined such a rehearing summarily in an unreported decision. This puts to rest any question over whether there is a split in Federal Circuit authority on this issue. Furthermore, the decision to decline rehearing *en banc* suggests that this issue was not considered to be of exceptional importance to the members of the Federal Circuit.

It is also worth noting that when this issue was decided against a major research-based pharmaceutical company in the *Warner-Lambert* case, that company did not elect to petition for rehearing *en banc*, or to petition for a writ of certiorari as Allergan has done here. One would have expected such activity by this party if the *Warner-Lambert* decision would truly lead to the dire consequences that petitioner Allergan predicts.

B. Research-Based Drug Patent Owners Are Not Left Without Incentives To Research and Develop New Uses For Existing Drugs

Petitioner over-inflates the importance of the issue raised by its petition by arguing that the Federal Circuit's decision "essentially destroys patent protection" and "severely undermines financial incentives for developing important new uses for existing drugs." Petition at 13-14. To the contrary, there is nothing in the Hatch-Waxman Act that would preclude companies like petitioner from bringing a traditional infringement suit against generic companies – once those companies have entered the market.

In other words, as long as a company such as petitioner Allergan has a good faith basis to support its allegations, it can bring a suit for induced infringement under 35 U.S.C. § 271(b) on the very same day that the generic company launches its drug product. If the patentee is concerned about immediate, irreparable harm, and it has the strong evidence to support such extraordinary relief, it can move for a temporary restraining order or a preliminary injunction. The only "remedy" that the Federal Circuit has deprived patentees such as petitioner of is the right to bring a ***preemptory*** lawsuit against a generic company, and to obtain an automatic 30-month stay of the ANDA process for ***all*** uses, with a patent directed to a use (1) that is not approved by the FDA, and (2) for which the generic company is not seeking approval.

Petitioner argues that it needs this preemptive relief as an incentive to innovate because the traditional patent infringement remedies are unsatisfactory. Petition at 16-17 ("remedy of a preliminary injunction is illusory at best" and

"nor does a damages remedy provide the assurance of recovery necessary to foster innovative new uses of drugs"). But the same complaints could be made by any patent holder, not just those in the pharmaceutical industry. The reality is that the threat of an infringement action ***will*** deter a generic drug manufacturer from taking actions that would render it liable for inducement to infringe. The cost to a generic company of constructing manufacturing facilities and gearing up to distribute a new product is far from insignificant. The threat of losing the value of this investment through an injunction, or the threat of being put out of business by incurring liability for a research-based drug company's lost profits, is more than enough encouragement to avoid infringing activities.

The heart of petitioner's concern seems to be not what generic companies will or will not do once their products are on the market, but how doctors will prescribe those drugs once they get their hands on them, since doctors are not bound by the labeling on the product. This repeated theme throughout Allergan's petition, while perhaps interesting, only serves to emphasize how misplaced its arguments are. The makers of generic drugs such as respondent B&L ultimately have no control over how doctors prescribe drugs, including whether they will choose to prescribe a given drug for an off-label use. Taking petitioner's arguments to their natural conclusion, the incentives of research-based drug companies will not be restored until generic companies are held to a strict liability standard under which, no matter how pure the motives of the generic companies, they are responsible for all infringing off-label uses of their drugs by doctors. Such a rigid requirement would certainly unduly suppress the flow of generic drugs to the consumer, and thus contravene the purposes of the Hatch-Waxman Act.

If petitioner is unhappy that doctors have the discretion to prescribe medications for off-label uses, perhaps it should look to address those concerns in a forum other than the courts.

The Federal Circuit's interpretation of section 271(e)(2) has not destroyed the incentives that would drive research-based drug companies to develop new uses of existing drugs. Petitioner is complaining because it lost a remedy that Congress never intended it to have, one that would artificially extend its patent monopoly to cover public domain drugs and public domain methods of using those drugs. There is no question, however, that petitioner, and research-based drug patent holders like it, can avail themselves of traditional patent infringement remedies if they have a good faith basis to do so.

II. The Federal Circuit's Interpretation Of 35 U.S.C. § 271(e)(2) Comports With Legislative History And Public Policy

The drug involved in this litigation, brimonidine, is in the public domain. Its use to lower intraocular pressure in glaucoma patients is also in the public domain. These facts are undisputed. Petitioner is essentially demanding, as "compensation" for its neuroprotection patents (which use is not approved by the FDA), the right to preclude (or at least to significantly delay entry into the market) a generic company's use of a public domain drug and method. As the Federal Circuit recognized in *Warner-Lambert*, any statutory interpretation that would allow this is inconsistent with "the stated purposes of the Hatch-Waxman Act, and would confer substantial additional rights on pioneer drug patent owners that Congress quite clearly did not intend to confer." 316 F.3d at 1359.

Warner-Lambert began its analysis by examining the plain language of section 271(e)(2), repeated in pertinent part here:

> It shall be an act of infringement to submit . . . [an ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

Focusing on the fact that Congress chose to use the word "the" before "use", instead of "a" or "any", the panel concluded that "the statutory language 'the use' is most reasonably interpreted to mean 'the use listed in the ANDA.' Congress could have been expected to use quite different language if it wanted to reach the opposite result." 316 F.3d at 1356.

The *Warner-Lambert* analysis did not end with the plain language, however. It is well established that when confronting ambiguous language in a statute, resort to the legislative history and policies underlying the statute are appropriate. *See, e.g., Oklahoma v. New Mexico*, 501 U.S. 221, 235 n.5 (1991) ("we repeatedly have looked to legislative history and other extrinsic material when required to interpret a statute which is ambiguous"); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990). *Warner-Lambert* went on to analyze portions of the legislative history of the Hatch-Waxman Act, [illegible]ding statements in the House Reports that demonstrated Congressional intent to limit the remedies

of section 271(e)(2) to patents that claim a method of use for which the ANDA applicant is seeking approval. 316 F.3d at 1359-60 ("Congress made it clear that the ANDA applicant need not certify with respect to every 'use' patent . . . Rather, the applicant needs only to certify with respect to use patents that claim an indication *for which the applicant is seeking approval to market the drug*."). The Federal Circuit also examined other parts of the statutory framework arising from the Hatch-Waxman Act, and found that language to be consistent with its interpretation of section 271(e)(2). *Id.* at 1360-62.

Finally, *Warner-Lambert* considered public policy concerns and found those to favor its interpretation of section 271(e)(2). In particular, the panel found that the appellant's interpretation of section 271(e)(2), which is the same as that advocated by both petitioner and the concurring *Allergan* opinions below ("the *Allergan* concurrences"), would effectively bar generic drug manufacturers from bringing public domain products and their public domain uses to the market, a result in direct conflict with the expressed Congressional purpose of making available "more low cost generic drugs." *See id.* at 1359. *Warner-Lambert* thus premised its interpretation of section 271(e)(2) on a reasoned analysis of all the applicable authorities, including the plain language of the statute, other statutory language within the Hatch-Waxman Act framework, legislative history, and public policy concerns.[2]

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2. Indeed, as noted above, the *Warner-Lambert* decision was so well-reasoned that none of the parties (which included a major pharmaceutical company) saw fit to file a petition for panel rehearing, a petition for rehearing *en banc*, or even a petition for writ of *certiorari*.

Drawing support from the *Allergan* concurrences, petitioner would interpret section 271(e)(2) in a manner directly contrary to the *Warner-Lambert* decision and yet, dismiss with little consideration much of the legislative history and policy concerns raised by *Warner-Lambert*. This is not an oversight; rather, both petitioner and the *Allergan* concurrences find the language of section 271(e)(2) so plain and unambiguous as to require no resort to public policy or legislative history. Respondent submits that this deliberate decision to pass over the legislative history and public policy issues, in the face of the *Warner-Lambert* panel's contradictory interpretation of the statue, undermines petitioner's position and reveals the weakness of the *Allergan* concurrences.

The language of section 271(e)(2) is, at best, ambiguous. After all, what better case of ambiguity could there be than two different three-judge panels of the Federal Circuit reaching diametrically-opposed conclusions as to the "plain meaning" of the same statutory language? Despite their knowledge of the contrary *Warner-Lambert* decision, petitioner and the *Allergan* concurrences would rest on their conclusion that the language of section 271(e)(2) is plain on its face and thus refuse to fully address contrary legislative history and policy concerns. The prevailing interpretation of the Federal Circuit, which is backed by a full analysis of the legislative history and policy concerns surrounding the Hatch-Waxman Act, is the correct one.

The Federal Circuit's interpretation of section 271(e)(2) finds support in recent amendments to FDA regulations. In the June 18, 2003 Federal Register, the FDA published

the following amendment to its patent submission and listing requirements for NDAs:

> For patents that claim a method of use, the applicant shall submit information only on those patents that claim indications or other conditions of use ~~of a~~ ***that are described in the*** pending or approved application. ***The applicant shall separately identify each pending or approved method of use and related patent claim.***

68 Fed. Reg. 36,704 (2003)[3] (new text shown in bold and italics, deleted text with strikethrough). The FDA explained its rule amendment as follows:

> All of the benefits afforded NDA holders under the Hatch-Waxman Amendments, such as the 30-month stay, derive from obtaining our approval of a particular drug product. Accordingly, only method-of-use patents that claim a use of the drug product in the pending or approved application must be submitted. Method-of-use patents for uses that the NDA holder "has not chosen to make available to the public" must not be submitted for listing.

68 Fed. Reg. 36,681 (citation omitted). This clarified rule and explanation make it abundantly clear that patents covering off-label uses should not be submitted to the FDA for listing in the Orange Book, and it follows that such patents cannot serve as the basis of an infringement action under section 271(e)(2). Notably, the FDA's rule amendments were,

3. Available at *http://www.fda.gov/OHRMS/DOCKETS/98fr/061803a.pdf.*

at least in part, a response to the FTC study entitled "Generic Drug Entry Prior to Patent Expiration" which petitioner cites to support its position that the Federal Circuit's interpretation is wrong. *See* 68 Fed. Reg. 36,677; Petition at 20.

Another policy concern supporting the Federal Circuit's rejection of petitioner's interpretation of section 271(e)(2) is that it would lead to abusive practices by research-based drug companies:

> If Warner-Lambert's interpretation were correct, for example, an NDA holder would be able to maintain its exclusivity merely by regularly filing a new patent application claiming a narrow method of use not covered by its NDA. It would then be able to use § 271(e)(2)(A) as a sword against any competitor's ANDA seeking approval to market an off-patent drug for an approved use not covered by the patent. Generic manufacturers would effectively be barred altogether from entering the market.

Warner-Lambert, 316 F.3d at 1359.

Petitioner made these concerns a reality. In October 2002, while petitioner's Federal Circuit appeal was pending, petitioner obtained yet another, new, neuroprotection patent which it subsequently listed in the FDA's "Orange Book." *See Alcon Labs., Inc. v. Allergan, Inc.*, 256 F. Supp. 2d 1080, 1083 (C.D. Cal. 2003). Disturbingly close to the *Warner-Lambert* panel's prediction, petitioner's "new" patent is a slightly narrower (in claim scope) version of its other two patents which cover the use of brimonidine for neuroprotection. Once respondent B&L had filed the requisite

certification that it would not infringe this newly-listed patent after its ANDA were approved, petitioner filed yet another suit against B&L (and also against respondent Alcon) under section 271(e)(2) (this time in ***Delaware*** instead of the forum of the original case, California). *Id.*

Of course, petitioner's act of simply filing suit triggered another automatic 30-month stay of the ANDA approval process. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Respondents successfully moved to have the case transferred back to California, and the district court has now entered judgment against petitioner on this new patent, based on reasoning similar to that in its original opinion as well as on the *Warner-Lambert* decision. *See Alcon*, 256 F. Supp. 2d 1080. Petitioner Allergan was "gaming" the system in exactly the manner that *Warner-Lambert* feared. If the Federal Circuit's *Warner-Lambert* interpretation is reversed, these types of abusive practices will continue.

In the end, there are strong legislative history and policy concerns supporting the Federal Circuit's interpretation of section 271(e)(2). The Federal Circuit's decision put to rest the abusive practices of companies such as petitioner which, by improperly expanding their patent rights, effectively recapture a drug and its use from the public domain (thus keeping less-costly versions of the drug out of the hands of consumers), which Congress could not have meant to do and indeed which Congress likely does not have the power to do. *See Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966) ("Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available."). In short, the Federal Circuit had it right when it held that an off-label use patent cannot serve as the basis for an infringement action under section 271(e)(2).

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted,

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No. 03-443

IN THE

Supreme Court of the United States

ALLERGAN, INC. AND ALLERGAN SALES, INC.,
Petitioners,

v.

ALCON LABORATORIES, INC., ALCON RESEARCH LTD., ALCON UNIVERSAL, LTD., AND BAUSCH & LOMB INCORPORATED,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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REPLY BRIEF IN SUPPORT OF PETITION

Respondents and their *amicus* argue that the decision below is not worthy of review because there is no split of authority over the issue presented. But that cannot be the standard where, as here, the Federal Circuit has exclusive jurisdiction over an issue. Rather, this Court has made clear that it will grant review of such cases where the issue is important, there is a clear division of views within the Federal Circuit, and there is strong evidence that the issue was decided incorrectly. All three factors are plainly present here.

Nor is there any merit to the claim that a recent Food and Drug Administration ("FDA") regulation renders the issue presented unimportant. That regulation is based on the same erroneous decisions that are the subject of this petition. The fact that the Federal Circuit's misconstruction of § 271(e)(2) has now infected regulations implementing other provisions of the statute underscores the need for this Court's review.

1. As petitioner has shown, the proper interpretation of § 271(e)(2) has profound implications for the public's health and welfare. By ruling that § 271(e)(2) does not protect patents that cover either "off-label" uses or only one of several uses approved by the FDA, the Federal Circuit has effectively destroyed the incentives for discovering and developing new, potentially life-saving uses of existing drugs. Respondents have completely failed to refute this showing.

The harms to innovation that the decision below will cause result from several indisputable realities of the drug industry. First, discovering and developing new uses for existing drugs is a time-consuming and expensive endeavor. Pet. 15. Patent protection is thus essential to fostering such development efforts. Second, physicians can and often do prescribe drugs for uses other than those the FDA has approved; indeed, "off-label" use is frequently state-of-the-art medicine. *Id.* at 6-7. As a result, where a pioneer develops a commercially

valuable, patented new use for an existing drug, generic manufacturers can seek FDA approval for a previously approved use knowing the drug can be prescribed for the patented, off-label use. Where a generic manufacturer induces physicians to prescribe its drug for an infringing off-label use, the pioneer suffers an immediate and enormous loss of the profits necessary to recoup its research and development investment. *Id.* at 16.

The purpose of this lawsuit was to prevent precisely this type of injury. Without any discovery, petitioner adduced enough publicly available evidence "to present a triable issue of fact" concerning respondent Alcon's induced infringement, "or at the least [to] allow [petitioner] to conduct discovery." Pet. App. 53a. Nontheless, petitioner's suit was dismissed because the Federal Circuit had concluded in a prior opinion that § 271(e)(2) cannot be used to prevent the harm of induced infringement by an ANDA holder, no matter how much evidence of such harm the patentee presents.[1]

Respondents now blithely assert that "all of the traditional remedies for patent infringement are still available to . . . patent holders [such as petitioner], which provide more than enough incentive for them to research new uses of existing drugs." B&L Opp. 2; see also Alcon Opp. 21 (patentee can "enforce a method-of-use patent after the FDA approves" an ANDA); GPhA Br. 10 (same). But respondents nowhere address, let alone refute, petitioner's showing that, once an ANDA is approved and physicians begin prescribing the generic drug for off-label use, it is virtually impossible to obtain a preliminary injunction barring such use. Pet. 16-17. Respondents likewise fail to address petitioner's showing that a post-infringement damages remedy is inadequate because

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[1] Thus, respondents' arguments about the supposed inadequacies of the record regarding off-label use of brimonidine for neuroprotection, respondents' awareness of that use, and their intent to induce such use, *see* Alcon Opp. 7 n.4, 8 n.5; B&L Opp. 8-9, are utterly irrelevant.

generic manufacturers typically lack the assets necessary to restore the pioneer's lost profits. *Id.* at 17.

Contrary to B&L's claim, these are *not* harms that could befall "any patent holder." B&L Opp. 13. Because drugs, like medical devices, are essential to promoting health and saving lives, those who hold patents on methods of using drugs face unique public policy barriers to preliminary injunctive relief, regardless of the strength of their cases on the merits. Pet. 17 n.5. Similarly, because of the very large disparity in the capitalization of pioneers, who make huge investments in research and development, and most generic manufacturers, who free-ride on those investments, pioneers are uniquely unlikely to collect full compensation from infringers. These unique harms cannot be brushed aside with assurances that generic manufacturers are unlikely to infringe at all, B&L Opp. 13, as the facts of this very case show.

Nor is true that patent term restoration alone provides adequate incentives for innovation. GPhA Br. 9. Term restoration merely compensates for years of patent protection lost during clinical testing and the NDA review process. Before that testing and review can even begin, however, pioneers must first discover and develop new uses for existing drugs. Such breakthroughs require enormous investments, Pet. 15. Yet, under the Federal Circuit's crabbed reading of § 271(e)(2), pioneers have no way of recouping these very investments, which the patent laws are designed to foster.

It is no answer to suggest that pioneers can protect such investments by obtaining NDAs on their new uses. GPhA Br. 9. Once the FDA approves an NDA for an initial use of a drug, manufacturers can submit ANDAs for just that initial use. After such ANDAs are granted, however, physicians can prescribe the generic for any use. Thus, once the generic enters the market, a pioneer's exclusive right to label for a second, FDA-approved use is meaningless: physicians can and will prescribe the generic for the second approved use, even though the ANDA did not approve the generic for that

use. See Pet. 17-18.[2] For the reasons recited above, moreover, any infringement action brought after the generic enters the market is a wholly inadequate remedy.

Unlike respondents, Congress recognized these harms, which is why the Hatch-Waxman Act's patent-related provisions ensure that infringement disputes regarding a generic drug covered by a valid use patent are resolved before the FDA gives marketing approval to the generic. Pet. 4-5, 18-19. Because the Federal Circuit's binding interpretation of § 271(e)(2) frustrates this scheme and irrefutably destroys the incentives necessary to discover and develop new uses of existing drugs, the issue presented is an exceptionally important one. Indeed, its importance is confirmed by the lengthy criticisms leveled at the *Warner-Lambert* decision by the panel below, by the criticisms the Federal Trade Commission leveled at the district court decision below, and by the participation of *amici*, including the generic drug trade association, at the petition stage of this case. This Court's review of such an important issue is plainly warranted.

2. The clear divergence of views within the Federal Circuit over the proper interpretation of § 271(e)(2) is an additional factor that counsels strongly in favor of review. See Pet. 19-20 (citing cases in which this Court has noted divergence of views in the Circuit when granting certiorari). The suggestion that the lack of dissent from the denial of rehearing below somehow reflects unanimity in the Federal Circuit, or a belief that the issue is unimportant, B&L Opp. 11; Alcon Opp. 11, 23; GPhA Br. 5, is frivolous. The panel members below took the remarkable step of detailing the analytical flaws in the *Warner-Lambert* decision and explaining why it frustrated Congress's intent. Their failure to repeat this showing in

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[2] These realities, not some nefarious "strategi[c] deci[sion]," GPhA Br. 9, led petitioner not to seek an NDA for neuroprotective use of brimonidine.

dissents on rehearing in no way reflects a retreat from their prior, published criticisms.[3]

3. Respondents' attempts to rebut those criticisms likewise provide no basis for denying review. As petitioner has shown, the *Warner-Lambert* panel engaged in an undisguised amendment of the statute. It read the statutory phrase "[an ANDA] for a drug . . . the use of which is claimed in a patent," 35 U.S.C. § 271(e)(2)(A), to mean "[an ANDA] for a drug . . . the use of which is claimed in a patent *and is listed in the ANDA*." See *Warner-Lambert Co.* v. *Apotex Corp.*, 316 F.3d 1348, 1356 (Fed. Cir. 2003). Respondents reiterate *Warner-Lambert*'s assertion that the phrase "*the* use . . . claimed in a patent" must refer to the use "listed in the ANDA" because that is the only use the FDA can approve. B&L Opp. 15; Alcon Opp. 13. But this is a question-begging tautology. Although a generic can be approved only for the use "listed in the ANDA," it can be prescribed for other uses and can thereby infringe patents claiming off-label uses. The scope of the FDA's approval authority, therefore, says nothing whatever about whether Congress intended to permit § 271(e)(2) actions for such patents. An intent to foreclose such actions cannot be inferred from Congress's decision to use the phrase "the use" instead of the phrase "a use."

Moreover, despite their insistence that the phrase "the use" be read in context, respondents—like the *Warner-Lambert* panel—fail to address other provisions of the Hatch-Waxman Act that squarely refute such a reading. First, in authorizing patent term restoration, the Act provides that, for use patents, any restoration must be "limited to any use claimed by the patent *and approved for the [drug]*." 35 U.S.C. § 156(b)(2)

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[3] The fact that rehearing was not sought in *Warner-Lambert*, B&L Opp. 16 n.2., is irrelevant. Unlike petitioner, Warner-Lambert failed to proffer adequate evidence of inducement to prevail under any interpretation of § 271(e)(2). *See* Pet. App. 26a (Schall, J., concurring). Accordingly, seeking rehearing would have been a vain act for Warner-Lambert.

(emphasis added). Thus, Congress plainly knew how to specify uses that are both "claimed" in a patent and "approved" by the FDA. The fact that it did so in other provisions of the very same Act, but not in § 271(e)(2), is fatal to any effort to read the additional qualification of an "approved" use into the latter provision. See, *e.g.*, *Russello* v. *United States*, 464 U.S. 16, 23 (1983).

Second, the *Warner-Lambert* panel's interpretation is flatly contradicted by the Act's certification and statement provisions. These provisions require an ANDA filer to make one of four certifications for a patent "which claims a use for [the] listed drug," including, if applicable, a certification

> (IV) that such patent is invalid or *will not be infringed* by the manufacture, use, or sale of the new drug for which [the ANDA] is submitted, *and*
>
> (viii) if with respect to the listed drug . . . information was filed . . . for a method of use patent *which does not claim a use for which the applicant is seeking approval under this subsection*, a statement that the method of use patent does not claim such a use.

21 U.S.C. § 355(j)(2)(A)(vii) & (viii) (emphases added). The conjunctive "and" makes indisputably clear that, even where a listed method of use patent "does not claim a use for which the applicant is seeking approval," an ANDA filer must submit *both* a paragraph (IV) certification *and* a subsection (viii) statement. Because a paragraph (IV) certification is the triggering event for a § 271(e)(2) action, and because the Act requires such certifications even where the listed patent does not claim the use for which approval is sought, § 271(e)(2) cannot be construed to bar suit whenever a use patent does not claim the use listed in the ANDA.

Respondents and their *amicus* do not even address these showings. Instead, Alcon claims that its fatally flawed reading is confirmed by the patent listing provision, which requires NDA applicants to submit information on "any

patent . . . which claims a method of using [the] drug and with respect to which a claim of patent infringement could reasonably be asserted." 21 U.S.C. § 355(b)(1). According to Alcon, "the *only* patents" that "could *reasonably* be asserted in the ANDA context"—and thus the only patents that should be listed—"are patents which claim the use for which an ANDA seeks approval." Alcon Opp. 16 (first emphasis added). But, as just noted, Congress *expected* NDA applicants to list patents that do *not* cover FDA approved uses. See 21 U.S.C. § 355(j)(2)(A)(viii) (requiring statement when "information was filed under [the listing provision] . . . or a method of use patent which does not claim a use for which the applicant is seeking approval"); see also *Apotex, Inc.* v. *Thompson*, No. 02-1295, 2003 WL 224277722, at *7 (Fed. Cir. Oct. 27, 2003) (under the listing provision, use patents should be listed "if it is reasonable to conclude that a person who makes, uses, or sells the drug would infringe").[4] And, as petitioner and Judge Schall have shown, patents on off-label uses *can* "reasonably be asserted" against ANDA filers who actively induce post-approval infringement.

Thus, both the plain language of § 271(e)(2) and its statutory context confirm that a patentee can bring an infringement action upon the filing of an ANDA "for a drug . . . the use of which is claimed in a patent," whether or not the ANDA seeks approval for the patented use. Neither the Act's purposes nor its legislative history remotely justify a departure from this plain meaning.[5] See, *e.g.*, *Garcia* v.

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[4] If Congress believed that only use patents claiming approved uses could be asserted in the ANDA context, it would have simply required the listing of use patents that claim "the method of using the drug specified in the NDA," since those are the only uses for which an ANDA applicant can seek approval.

[5] The existence of *Warner-Lambert*'s mistaken interpretation does not, as Alcon claims, Alcon Opp. 14, render § 271(e)(2) ambiguous. *See, e.g.*, *Ingalls Shipbuilding, Inc.* v. *Director, Office of Workers' Comp. Programs*, 519 U.S. 248, 254-55, 261 (1997) (granting review to resolve

United States, 469 U.S. 70, 75 (1984) ("the most extraordinary showing of contrary intentions" is required to override plain language). In fact, both are consistent with the interpretation that the panel below would have adopted.

Giving § 271(e)(2) its plain meaning does not frustrate Congress's intent to foster legitimate generic competition. Contrary to the claims of respondents (and the *Warner-Lambert* panel), pioneers cannot "strangle generic competition" simply by acquiring narrow patents on off-label uses and using them to block ANDAs seeking approval for different uses. Alcon Opp. 22; see also B&L Opp. 16. Rather, owners of such patents must be able to allege in good faith, and to prove, not only that the generic drug could be prescribed for the patented use, but also that the ANDA applicant *is affirmatively inducing that infringing use*. See Pet. App. 26a (Schall, J., concurring) (petitioner stated a valid claim because it alleged that respondents were "promot[ing]" infringing uses).[6] Thus, pioneers can employ method of use patents as "swords" *only* against generic manufacturers who engage in illegal competition. There is nothing "absurd" about barring those who seek to compete illegally from entering the market, and doing so will not bar entry by others who do not induce unlawful infringement.[7]

Nor do references in the House Report to "controlling use patents"—*i.e.*, those that claim the use specified in the

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circuit split on meaning of statute and concluding the plain language controlled); *see also Reno* v. *Koray*, 515 U.S. 50, 64 (1995) ("A statute is not ambiguous for purposes of lenity merely because there is a division of judicial authority over its proper construction.") (internal quotation marks omitted).

[6] Accordingly, liability can be imposed in a § 271(e)(2) suit based only on intentional inducement and not, as B&L hysterically claims, on a "strict liability standard . . . for all infringing off-label uses." B&L Opp. 13.

[7] It also will not enable petitioner to "retain the exclusive rights to all uses of" brimonidine, including an unpatentable use. Alcon Opp. 21.

NDA—justify *Warner-Lambert*'s refusal to give § 271(e)(2) its plain meaning. The Report does *not* state that "controlling use" patents are the "only" use patents for which a certification is ever required, as respondents misleadingly claim. See Alcon Opp. 17. Indeed, the fact that Congress understood the concept of "controlling use" patents but did not use that concept in the statute itself undermines any effort to imply such a limitation in § 271(e)(2). See Pet. App. 24a (Schall, J., concurring). Moreover, the Report explains that where a drug is approved for two indications and an ANDA seeks approval "only for Indication No. 1, and not Indication No. 2 because it is protected by a use patent, then the applicant must make the appropriate certification and a statement explaining that it is not seeking approval for Indication No. 2." H.R. Rep. No. 98-857, pt. 1, at 22 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2655. In this example, any use patent claiming indication No. 2 is not a "controlling" use patent because it does not claim the use for which the applicant seeks approval (indication No. 1). Nevertheless, the Report explains that the ANDA filer must make both an "appropriate certification" and a statement concerning the non-"controlling use" patent, which is consistent with the Act's certification and statement provisions. See *supra* at 7.[8]

4. Finally, there is no merit to respondents' claim that the FDA's recent amendment of its patent listing regulations strips the Federal Circuit's interpretation of § 271(e)(2) of any continuing legal importance. In explaining why it was limiting Orange Book listings to method of use patents "that claim indications or other conditions of use that are described in the pending or approved [NDA]," Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676, 36,704 (June 18, 2003) (to be codified at 21 C.F.R. § 314.53(b)), the FDA expressly relied on the very same erroneous Federal

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[8] The Report's reference to an "appropriate certification" distinguishes between the four mutually exclusive certifications set out in paragraphs (I) through (IV), not between the two use patents in the example.

Circuit decisions that are the subject of this petition. See *id.* at 36,681-82 (citing *Warner-Lambert* and the per curiam decision in this case as support for its regulation). The importance of the issue presented by this case—and the necessity of review by this Court—is thus underscored, not diminished, by the fact that a federal agency has relied on the lower court's erroneous interpretation in implementing a related statutory provision.

Indeed, had the Federal Circuit interpreted § 271(e)(2) correctly in *Warner-Lambert* and in this case, the FDA could not have issued a regulation limiting Orange Book listings to use patents that claim only FDA-approved uses. Faced with a judicial determination that patents claiming off-label uses *can* be enforced in § 271(e)(2) actions, the FDA would have had to permit the listing of patents claiming such uses. Otherwise, the judicially recognized right to enforce such patents under § 271(e)(2) would have been rendered nugatory by an agency that has no authority to interpret or implement that provision.

In short, it is the Federal Circuit's erroneous interpretation of § 271(e)(2) that precludes enforcement of patents on off-label uses and, by doing so, destroys the incentives for research into new uses of existing drugs—the principal area of innovation in the pharmaceutical industry today. The health of millions of Americans depends upon the proper resolution of the issue presented by this case. The stark division of opinion among the judges on a specialized court of appeals as to the proper interpretation of § 271(e)(2) cries out for this Court's review.

CONCLUSION

For the foregoing reasons, and those set forth in the petition, this Court should grant the petition for a writ of certiorari to the Federal Circuit.

Respectfully submitted,

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IN THE
Supreme Court of the United States

ALLERGAN, INC., and ALLERGAN SALES, INC.,
Petitioners,

v.

ALCON LABORATORIES, INC.; ALCON RESEARCH, LTD.;
ALCON UNIVERSAL, LTD.; and
BAUSCH & LOMB INCORPORATED,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Whether 35 U.S.C. § 271(e)(2) permits a patent holder to bring an infringement action upon the filing of an Abbreviated New Drug Application ("ANDA") "for a drug . . . the use of which is claimed in a patent," as the plain language of the statute states, or whether such an action can be brought only upon the filing of an ANDA "for a drug . . . the use of which is claimed in a patent *and is listed in the ANDA*," as the Federal Circuit ruled below.

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a public interest law and policy center with supporters in all 50 states.[1] WLF devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government. In particular, WLF has appeared in numerous federal and state courts in cases raising issues related to health care delivery. *See, e.g., Pharmaceutical Research and Manufacturers of America v. Walsh,* 123 S. Ct. 1855 (2003). WLF successfully challenged the constitutionality of Food and Drug Administration (FDA) restrictions on speech regarding off-label uses of FDA-approved products. *Washington Legal Found. v. Friedman,* 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd,* 202 F.3d 331 (D.C. Cir. 2000).

WLF has appeared in numerous cases related to the proper resolution of drug patent disputes. *See, e.g., Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001), *cert. denied*, 537 U.S. 941 (2002) (Hatch-Waxman Act procedures for resolving drug patent disputes). WLF also filed a brief in this case when it was before the Federal Circuit.

WLF is concerned that the decision of the Federal Circuit, if allowed to stand, will significantly impair the ability of patent holders to file suit in federal court to protect their patents against infringement. There is no dispute that

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[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, contributed monetarily to the preparation and submission of this brief.

Petitioners hold a valid method-of-use patent that covers a use for the drug brimonidine whose value is widely recognized within the medical profession; indeed, the evidence suggests that the patented use accounts for a significant majority of prescriptions written for the drug. Yet the Federal Circuit has held that Petitioners may not sue under the Hatch-Waxman Act to prevent competitors from inducing infringement of that patent.

WLF believes that the patent system is an important tool in providing pharmaceutical companies with the necessary financial incentives to gamble the substantial sums necessary for the development of new, life-saving therapies. WLF fears that the decision below significantly undermines those incentives.

WLF has no direct interest in the outcome of this case or any related cases. WLF takes no position on the underlying patent dispute between Petitioners (hereinafter "Allergan") and Respondents (hereinafter "Alcon" and "Bausch & Lomb"). WLF is filing this brief solely because it believes that the district court improperly applied the procedures established by the Hatch-Waxman Act for resolving pharmaceutical patent disputes.

WLF is filing with the consent of all parties. The written consents have been lodged with the Clerk of the Court.

STATEMENT OF THE CASE

WLF hereby adopts by reference the Statement of the Case set forth in the Petition. In brief, this case involves a dispute between a pioneer drug manufacturer (Allergan) and two generic drug manufacturers (Alcon and Bausch & Lomb) regarding Alcon's and Bausch & Lomb's proposed sale of

brimonidine, a drug used to treat open-angle glaucoma, a disease of the eye. In September 1996, Allergan obtained Food and Drug Administration (FDA) approval for the manufacture and sale of brimonidine for the purpose of lowering intraocular pressure ("IOP") in patients with open-angle glaucoma. At the time that FDA approved Allergan's New Drug Application ("NDA"), it was generally thought within the medical profession that glaucoma was caused by abnormally high IOP, which pushed against -- and thereby damaged -- the optic nerve. Pet. App. 46a. Allergan marketed its product under the trade name Alphagan; the product soon became a leading drug to treat glaucoma. *Id.*

The Food, Drug, and Cosmetics Act (FDCA) grants the holder of an approved NDA a five-year period of exclusivity in marketing its drug. 21 U.S.C. § 355(c)(3)(D)(ii). Allergan's exclusivity period for brimonidine was extended for six months pursuant to 21 U.S.C. § 355a(a)(1)(i) (which permits extensions based on manufacturer testing of a product's safety and efficacy in children); thus, its exclusivity period expired in March 2002.

In recent years, the medical profession has changed its views considerably regarding the causes of glaucoma. Pet. App. 46a. Scientists discovered that patients with lowered IOP were still contracting glaucoma; they thus concluded that open-ended glaucoma is a neurodegenerative disease that originates in the optic nerve itself. *Id.* Accordingly, scientists began looking for ways to prevent glaucoma by treating the optic nerve directly, *i.e.*, neuroprotection.

In the early 1990s, researchers at Allergan discovered that brimonidine has significant neuroprotective properties; *i.e.*, the optic nerve and other nerve cells are rendered less susceptible to injury and degeneration when treated with

brimonidine. *Id.* at 47a. That discovery caused many doctors to conclude -- under the more recent view that glaucoma is a neurodegenerative disease -- that brimonidine is effective in treating glaucoma because of its neuroprotective qualities. Based on its discovery, Allergan obtained two method-of-use patents (the "'415 Patent" and the "'741 Patent") that claim a method of using brimonidine as a neuroprotective agent to treat glaucoma. *Id.* at 50a.

Alcon and Bausch & Lomb filed Abbreviated New Drug Applications (ANDAs) with FDA in October 2001, seeking permission to sell brimonidine (following the expiration of Allergan's exclusivity period) for use in reducing IOP. *Id.* Congress created the ANDA procedure in 1984 as part of the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act. *See* 21 U.S.C. § 355(j). The Hatch-Waxman Act was Congress's attempt to strike a balance between the competing interests of pioneer and generic drug manufacturers. The Act benefited generic manufacturers by creating the ANDA procedure, which greatly streamlined the process by which generic manufacturers can receive FDA approval to market generic copies of pioneer drugs. 21 U.S.C. § 355(j). The Act also benefited generic manufacturers by amending patent law to allow them to use patented products in connection with studies designed for the purpose of obtaining FDA approval of an ANDA; that amendment allowed generic manufacturers to begin product testing before expiration of the patent. 35 U.S.C. § 271(e)(1). The Act benefited pioneer manufacturers by granting patent-term extensions under certain circumstances. 35 U.S.C. § 156.

The Act also set forth procedures for resolving patent disputes between pioneer and generic manufacturers. Those procedures are set forth in § 505(j) of the FDCA, 21 U.S.C. § 355(j). The FDCA provides that FDA is to maintain a list of

FDA-approved drugs and to include on that list any patent information respecting those drugs. 21 U.S.C. § 355(j)(7)(A). That FDA list is generally referred to as the "Orange Book." If a generic manufacturer seeks to market a generic version of an approved drug for which a patent is claimed in the Orange Book, the manufacturer must include in its ANDA a certification "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV).[2]

An ANDA that includes a Paragraph IV Certification and that is otherwise proper must be approved immediately by FDA unless the patent holder files an infringement action within 45 days of the date on which the applicant notifies the patent holder that a Paragraph IV Certification has been filed. 21 U.S.C. § 355(j)(5)(B)(iii). If an infringement action is filed within that 45-day period, then the FDCA provides:

> [T]he approval [of the ANDA] should be made effective upon the expiration of the thirty-month period beginning on the date of the receipt [by the patent holder of notice of the Paragraph IV certification] or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that –
>
> (I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval should be made effective on the date of the court decision.

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[2] Such a certification is often referred to as a "Paragraph IV Certification."

Id.

As noted above, Alcon and Bausch & Lomb in October 2001 filed ANDAs seeking FDA permission to market brimonidine for the purpose of lowering IOP in open-angle glaucoma patients, in anticipation of the March 2002 expiration of Allergan's exclusivity period. Because Allergan had listed the '415 Patent and the '741 Patent in the Orange Book, Alcon and Bausch & Lomb included Paragraph IV Certifications in their ANDAs; those certifications indicated that the manufacture, sale, or use of their products would not infringe Allergan's patents because their products would be labeled only for use in lowering IOP, not for neuroprotection.

On January 9, 2002 -- within 45 days of receiving notice of Alcon's and Bausch & Lomb's Paragraph IV Certifications -- Allergan filed suit in federal district court under 35 U.S.C. § 271(e)(2). That section -- yet another provision added to federal law by the Hatch-Waxman Act -- establishes as "an act of infringement" the filing of an ANDA "for a drug claimed in a patent or the use of which is claimed in a patent," if the purpose of the ANDA is to obtain FDA approval for the manufacture, use, or sale of the drug "before the expiration of such patent." Allergan alleged that Alcon and Bausch & Lomb filed ANDAs not because they anticipated substantial sales for treatment of excessive IOP, but because they anticipated that many doctors would prescribe their products for neuroprotection. Allergan alleged that such prescriptions would infringe on its method of use patents, and that Alcon and Bausch & Lomb had already taken numerous actions designed to induce such infringement.

The district court granted summary judgment to Alcon, ruling that 35 U.S.C. § 271(e)(2) did not create a cause of action for Allergan's benefit. Pet. App. 45a-68a. The court

held that even accepting as true Allergan's allegation regarding Alcon's actions to induce infringement of Allergan's patents, Congress did not intend § 271(e)(2) to cover such situations. *Id.* The court later granted summary judgment to Bausch & Lomb on identical grounds.

In March 2003, the Federal Circuit affirmed, but it issued a highly unusual opinion. *Id.* 1a-44a. The three-judge panel's *per curiam* opinion held that the panel was bound by the interpretation of § 271(e)(2) set forth by a prior panel in *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003). *Warner-Lambert* had held in January 2003 that a method-of-use patent holder may not sue for patent infringement under § 271(e)(2) unless the alleged infringer has stated explicitly in its ANDA that it intends to market its product for the patented use. Although the panel felt bound by *Warner-Lambert* to affirm the dismissal of Allergan's § 271(e)(2) claim, all three panel members joined concurring opinions stating their beliefs that *Warner-Lambert* was wrongly decided and indicating that they would have reinstated Allergan's claims had they been free to do so. Pet. App. 22a-44a.

Judge Schall, joined by Judge Clevinger, stated in an opinion concurring in the judgment only, "In my view, contrary to the conclusion reached in *Warner-Lambert*, a claim of induced infringement like the one asserted by Allergan against Alcon and B&L is cognizable under 35 U.S.C. § 271(e)(2)." *Id.* at 22a (Schall, J., concurring in the judgment). Similar, Judge Linn stated, "In my opinion, the court in *Warner-Lambert* has ventured beyond our interpretive role and, in interpreting the complex statutory scheme before it, has allowed its policy choices and its evaluation of the legislative history -- reasonable as they may be -- to override

the terms of the statute chosen by Congress." *Id.* at 42a (Linn, J., concurring in the judgment).

REASONS FOR GRANTING THE PETITION

This case raises health care and patent issues of exceptional importance. If advances in health care are to continue, two competing interests must be properly balanced: (1) the public interest in a strong patent system that rewards innovation by providing exclusive marketing rights to those whose research and development expenditures result in the development of new therapies; and (2) the public interest in encouraging the marketing of generic versions of those new products (after expiration of an appropriate exclusivity period), thereby ensuring the competition necessary to produce lower prices. Congress attempted to strike a balance between those competing interests when, in 1984, it adopted the Hatch-Waxman Act. The decision below puts that balance seriously out of whack; the Court should grant review to restore the balance intended by Congress.

The language of § 271(e)(2) could not be plainer that a patent holder situated as is Allergan is permitted to file suit in federal court, based on claims that a generic drug manufacturer is inducing others to infringe the patent, whenever the generic manufacturer files an ANDA for a drug the use of which is covered in the patent. The Federal Circuit's refusal to enforce the statute as written appears to be based on the fact that the patented use for brimonidine is an off-label use (*i.e.*, Allergan's FDA-approved labeling for Alphagan does not include neuroprotection). But as this Court has repeatedly recognized, off-label use of FDA-approved products is a crucial component of the practice of medicine in this country. Often, the medical community recognizes that proper patient care *requires* the prescription of a drug for an off-label use; indeed,

the great majority of prescriptions written for brimonidine are written by doctors seeking to utilize its patented (but off-label) neuroprotective properties. By adopting a strained reading of § 271(e)(2) to deny a cause of action to pharmaceutical patent holders simply because the allegedly infringed use happens to be an off-label use, the Federal Circuit has significantly curtailed the ability of such patent holders to protect their property rights.

This diminution of patent rights in turn will have significant adverse health effects by reducing the incentive for companies to conduct the research necessary to develop new, life-saving therapies.

I. REVIEW IS WARRANTED BECAUSE THE DECISION BELOW THREATENS ADVANCES IN HEALTH CARE BY UNDERMINING INCENTIVES TO DEVELOP NEW, LIFE-SAVING THERAPIES

The Federal Circuit's refusal to permit Allergan and similarly situated patent holders to enforce their patent rights by bringing an action under § 271(e)(2) appears to have been based primarily not on the actual language of that statute, but rather on a belief that patents covering uses not approved by FDA are less worthy of protection than patents covering approved uses. *See, e.g., Warner-Lambert,* 316 F.3d at 1358 ("[I]f an innovator had not made the investment to test and obtain [FDA] approval of the new use, what investment is to be protected by creating an added incentive?"). That belief suggests that the Federal Circuit fails to appreciate the importance of off-label uses in health- care delivery and of the need to encourage research designed to discover such uses -- an importance recognized by this Court on several occasions.

Review is warranted because of the potential adverse health consequences of the decision below.

A. Off-Label Uses of FDA-Approved Products Play a Crucial Role in Health Care, and Patents Covering Such Uses Should Be Enforceable to the Same Extent as Patents Covering FDA-Approved Uses

When it approves a drug or medical device for introduction into interstate commerce, FDA reviews the product labeling. The labeling sets forth the indications approved by FDA. FDA requires such drugs or devices to bear labeling which lists their approved uses, and prohibits such labeling from listing any use that has not been approved by FDA. But FDA does not attempt to regulate the practice of medicine and thus does not attempt to regulate the uses doctors make of FDA-approved products. *See, e.g., Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341, 350-51 (2001).

Indeed, advances in medical care often stem from the discovery that new uses of FDA-approved drugs and devices can benefit patients otherwise lacking satisfactory treatment options. The medical community's knowledge regarding the safety and efficacy of FDA-approved products inevitably outpaces FDA-approved labeling. Physicians who regularly work with these drugs and devices, and researchers who study their utility in treating conditions or patient populations that are not included in the existing labeling, often learn that they can be used safely and effectively for purposes outside the labeling.

The diffusion of this knowledge can have important benefits for patients -- particularly patients faced with serious illnesses and few treatment options, or a range of treatment options that have already failed or proved unsatisfactory due

to low effectiveness or side effects that are hard to tolerate. In fields such as oncology, for example, a substantial number of medically-accepted treatments involve off-label uses of FDA-approved drugs.[3] Similarly, physicians have long relied extensively on off-label treatments in caring for patients with AIDS.[4] Were doctors limited to using FDA-approved products only as labeled, in many cases their patients would receive sub-optimal care.

The importance of off-label uses of FDA-approved products is by now universally accepted. Most importantly, both FDA and the Court have recognized the important role that off-label uses play in our health care system. *See, e.g., Buckman*, 531 U.S. at 351 n.5 ("'Off-label use is widespread in the medical community and often is essential to giving patients optimal health care, both of which medical ethics, FDA, and most courts recognize.'") (quoting Beck & Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions,* 53 FOOD & DRUG L.J. 71, 72 (1998)). *See also, Washington Legal Found. v. Friedman,* 13 F. Supp. 2d at 56.

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[3] *See, e.g.*, U.S. General Accounting Office, *Off-Label Drugs, Reimbursement Policies Constrain Physicians in Their Choice of Cancer Therapies,* GAO/PEMD-91-14 (Sept. 1991) (finding that 25% of cancer drugs were used off-label and that 56% of cancer patients were given at least one drug off-label).

[4] *See, e.g.*, Testimony of Sarah F. Jagger, General Accounting Office Director of Health Services Quality and Public Health Issues, before the House Government Reform Committee, Subcommittee on Human Resources, 1996 WL 520197 (F.D.C.H.) (Sept. 12, 1996) (citing research finding that more than 80% of AIDS patients received at least one drug off-label and that 40% of all drugs that were given were prescribed off-label).

Information about safe and effective off-label uses of FDA-approved products does not materialize on its own. Rather, reliable information can be developed only through pains-taking and expensive medical research. Funding for such research is far more easily obtained if investors reasonably believe that they can derive an economic return from their investment in research. Indeed, that is precisely the theory underlying our patent system: the law provides an economic incentive for new product development by ensuring (by means of restrictions on competition) that firms that invest in research and development of new products -- or new uses of existing products -- will be able to realize a return on their investment when their research and development expenditures bear fruit.

The decision below significantly reduces those financial incentives. It deprives pharmaceutical patent holders of an important means of preventing infringement of their patents, based solely on the fact that the patent covers a method of use that FDA has not approved for inclusion on the labeling of an FDA-approved product. The effect of that decision is not difficult to discern: firms will now be substantially less willing to invest in research and development of new uses for existing pharmaceuticals, and (in the not-too-distant future) the flow of information about such new uses will be reduced substantially. Review is warranted to determine whether Congress really intended to create a two-tiered patent regime whereby patents covering one important aspect of our health-care delivery system (those covering off-label uses of FDA-approved products) are afforded less protection than patents covering other aspects of that system.

B. Review Is Warranted Because the Decision Below Upsets the Balance Congress Intended to Create When It Adopted the Hatch-Waxman Act

When it adopted the Hatch-Waxman Act (of which § 271(e)(2), the statute at issue in this case, is an integral part), Congress intended to strike a balance between the rights of pioneer and generic drug manufacturers, to ensure that strong incentives remained in place for the development of new, life-saving therapies. Review is warranted because the decision below threatens to upset that balance and thereby undermine incentives for continued health-care advances.

The Hatch-Waxman Act provided several significant benefits to generic drug manufacturers, benefits designed to increase competition in drug sales. Most significantly, the Act created the ANDA procedure, which allows companies to obtain FDA marketing approval for a generic drug without conducting their own extensive safety and efficacy studies. An ANDA allows a generic company to obtain marketing approval by piggybacking on the studies submitted by the pioneer manufacturer when it submitted its NDA. *See* 21 U.S.C. § 355(j). The Act also allows a generic company to conduct tests on a patented drug for the purpose of preparing an ANDA in anticipation of the patent's expiration. 35 U.S.C. § 271(e)(1). By so providing, the Act overruled *Roche Products, Inc. v. Bolar Pharmaceuticals Co.*, 733 F.2d 858 (Fed. Cir. 1984), which held that using a patented drug for testing in order to prepare an application for FDA marketing approval was an infringing use. Pet. App. 55a.

Congress was careful, however, to maintain incentives for new product development by including several provisions in the Hatch-Waxman Act that benefited pioneer manufacturers. For example, the Act granted patent term extensions as

partial recompense for the years lost at the front end of the patent. 35 U.S.C. § 156.[5] Most importantly for purposes of this case, the Act created a procedure allowing pioneer manufacturers to protect their patents by filing infringement actions (and obtaining injunctive relief) even before competing generic companies begin marketing their products. 21 U.S.C. § 355(j)(2) & (5); 35 U.S.C. § 271(e)(2). That procedure (outlined above in more detail at 5-6) is a significant benefit to pioneer drug manufacturers; an injunction that prevents infringing actions is always preferable to an award of damages (which may or may not be collectible) after the infringing actions have occurred.

The decision below upsets the balance created by Hatch-Waxman by depriving pioneer manufacturers of this patent-enforcement mechanism in a significant number of suits. Under the Federal Circuit's decision, generic manufacturers are permitted to: (1) piggyback on a pioneer manufacturer's research in order to apply for an ANDA; and (2) conduct tests on the pioneer manufacturer's product regardless of any patents on the drug; yet pioneer manufacturers may not take advantage of the Hatch-Waxman Act's patent enforcement mechanisms in a significant number of suits, regardless how much evidence they may have that the generic company plans to market the drug in a manner that will infringe existing patents or will induce others to do so. Congress struck the balance achieved in the Hatch-Waxman Act in part to ensure that the patent rights granted to pioneer drug companies were sufficiently strong to ensure continued high levels of drug research.

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[5] Drug patent holders generally must wait five or more years from the time they initially obtain a patent until they receive approval of their NDA from FDA and thus can begin marketing their drug. By the time that the NDA is approved, a significant portion of a patent holder's exclusive marketing period has elapsed.

Review is warranted because the Federal Circuit's decision threatens to upset that balance by depriving pioneer drug companies of significant patent enforcement rights, thereby substantially reducing incentives to engage in research designed to develop new, life-saving therapies.

II. REVIEW IS WARRANTED BECAUSE THE APPEALS COURT'S DECISION CONFLICTS WITH THE PLAIN LANGUAGE OF § 271(e)(2)

Review is warranted for the additional reason that the Federal Circuit's decision is so plainly at odds with the express language of 35 U.S.C. § 271(e)(2). Indeed, all three members of the panel agreed that Allergan had stated a cause of action under § 271(e)(2) but felt constrained by the Federal Circuit's prior decision in *Warner-Lambert* to hold otherwise. Pet. App. 22a-41a; *id.* 42a-44a. Direct splits among the federal appeals courts are, of course, nearly impossible in patent cases because of the Federal Circuit's exclusive appellate jurisdiction. But the virtually unprecedented situation presented by this case -- a three-judge appeals court panel unanimously expressing its disagreement with another panel from the same circuit on a clear-cut issue of law -- is as close to a circuit split on an issue of patent law as the Court is ever likely to see.

The Court has repeatedly made clear that the primary, if not the exclusive, basis for interpreting a federal statute is the plain meaning of the actual language employed by Congress. *United States v. LaBonte*, 520 U.S. 751, 757 (1997) ("[W]e assume that in drafting this legislation, Congress said what it meant."). Section 271(e)(2) provides as follows:

> It shall be an act of infringement to submit [an ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission

> is to obtain approval under the [FDCA] to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

If one parses each clause of § 271(e)(2), one searches in vain for a requirement (imposed by the Federal Circuit) that a method of use patent holder demonstrate that the patented use is explicitly listed in the generic competitor's ANDA. To the contrary, Allergan's complaint fulfilled each of the statute's prerequisites for stating a claim that Alcon and Bausch & Lomb committed infringing acts when they submitted their ANDAs. First, the ANDAs submitted by Alcon and Bausch & Lomb were for a drug (brimonidine) "the use of which is claimed in a patent" (the '415 and '741 Patents). Second, the ANDAs were submitted for the purpose of obtaining FDA approval to "engage in the commercial manufacture, use, or sale" of brimonidine. Third, a method of using the drug that Alcon and Bausch & Lomb intend to market is claimed in Allergan's patents. Finally, Alcon and Bausch & Lomb intend to market brimonidine as soon as their ANDAs are approved; thus, the manufacture, use, or sale of generic brimonidine obviously will occur long "before the expiration of [the '415 and '741] patent[s]," which will not expire for many years to come.[6]

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[6] The act of infringement created by § 271(e)(2) has been referred to as "a highly artificial act of infringement," because it involves nothing more than the filing of a document with the government, not the manufacture, sale, or use of a patented product. *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). Meeting the prerequisites of § 271(e)(2) is sufficient to allow a patent holder to get his foot inside the federal courthouse door; but in order to succeed in his § 271(e)(2) claim, the patent holder must demonstrate that the defendant has filed a Paragraph IV Certification "that is in error as to whether commercial

(continued...)

The *Warner-Lambert* panel arrived at a contrary interpretation only by giving a tortured reading to the language of § 271(e)(2). Pointing to the penultimate clause of that provision (". . . the use of which is claimed in a patent . . ."), the panel stated that Congress's choice of the words "the use" rather than the words "a use" suggests reference to a particular use; the panel concluded that "the use" being referred to is "the use listed in the ANDA." *Warner-Lambert*, 316 F.3d at 1356. That conclusion is silly. The panel is correct that the choice of "the" rather than "a" indicates that Congress had an antecedent in mind. But the language of the clause quite clearly ties the words "the use" to uses claimed in the patent, not to uses listed in the ANDA. Because the use of brimonidine for neuro-protective purposes is the use claimed by Allergan in its patent, because the Respondents have filed an ANDA to sell a drug (brimonidine) "the use of which is claimed in a patent," and because Allergan alleges that Respondents have filed their ANDA with the intent of inducing others to infringe Allergan's patent, Allergan has stated a cause of action under § 271(e)(2). As Judge Schall cogently explained in his opinion below concurring in the judgment, the Federal Circuit's contrary interpretation of § 271(e)(2) cannot be squared with the language of that provision. *See* Pet. App. 23a-25a.

The issue that divided the two Federal Circuit panels -- whether 35 U.S.C. § 271(e)(2) creates a cause of action for infringing or inducing infringement of patents covering off-

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[6](...continued)
manufacture, use, or sale of the new drug (none of which, of course has actually occurred) violates the relevant patent." *Id.* WLF takes no position on whether Allergan could make such a showing; but § 271(e) indicates that Congress intended to permit pioneer manufacturers to go before a district court in an effort to make such a showing.

label uses of FDA-approved products -- is a recurring one, as is evidenced by the nearly simultaneous consideration of the issue in two separate Federal Circuit cases. Because the *Warner-Lambert* panel happened to issue its decision more quickly, its decision has created the controlling precedent in the Federal Circuit. Because that decision is so clearly at odds with the statutory language and is likely to have significant impact on the delivery of health care in this country, review by this Court is warranted.

CONCLUSION

Amicus curiae Washington Legal Foundation respectfully requests that the Court grant the petition for a writ of certiorari.

Respectfully submitted,

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(5)

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In the Supreme Court of the United States

ALLERGAN, INC. AND ALLERGAN SALES, INC.,
Petitioners,

v.

ALCON LABORATORIES, INC., ALCON RESEARCH, LTD., ALCON UNIVERSAL, LTD., and BAUSCH & LOMB, INC.,
Respondents.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF GENERIC PHARMACEUTICAL ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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BRIEF OF GENERIC PHARMACEUTICAL ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

With the consent of the parties, *amicus curiae* Generic Pharmaceutical Association ("GPhA") respectfully submits this brief in opposition to the petition for writ of certiorari.*

INTEREST OF *AMICUS CURIAE*

GPhA is a national trade association consisting of more than 140 member companies involved in the supply, manufacture, sale, and distribution of generic pharmaceuticals. GPhA advances its members' interests by advocating laws and regulations that encourage the sale of safe, effective, and affordable prescription drugs. This activity benefits the association's members as well as the pharmaceutical industry and the consuming public. In furtherance of its mission, GPhA prepares and disseminates accurate and reliable information about the pharmaceutical industry; participates in legislative, regulatory, and administrative proceedings affecting the industry; and promotes the correct and consistent interpretation by the courts and the U.S. Food and Drug Administration ("FDA") of laws that directly affect the manufacture, distribution, and sale of generic pharmaceutical products.

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* Counsel of record for the parties do not object to the filing of this brief. In accordance with this Court's Rule 37.2(a), those letters have been filed with the Clerk.

In accordance with Rule 37.6, *amicus* states that this brief was authored in its entirety by the counsel listed on the cover, and no person or entity other than the *amicus* listed on the cover made a monetary contribution to the preparation or submission of this brief.

GPhA has an abiding interest in the relationship between patent law and the abbreviated approval process for generic drugs. It seeks to assure that: (1) when patent rights expire, generic drugs can be marketed for all indications that are in the public domain or otherwise off-patent; and (2) the patent laws are not applied in a manner that frustrates Congress's intent to make generic drugs available to consumers upon the expiration of patents that claim the drug or its approved uses. Because the ultimate relief sought by Allergan threatens both these interests, GPhA has a significant stake here and respectfully opposes the petition.

SUMMARY OF THE ARGUMENT

In the *per curiam* decision below, a unanimous panel of the United States Court of Appeals for the Federal Circuit affirmed summary judgment for the defendants based on the precedential holding in *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003). There, a unanimous panel held that an action for infringement under 35 U.S.C. § 271(e)(2)(A)—which triggers the automatic 30-month stay of FDA approval of the generic manufacturer's proposed product—is limited to method-of-use patents that claim a use of the NDA drug for which the NDA-holder has actually made the investment to obtain FDA approval. Patents on unapproved, or "off-label," uses (like the patents at issue here and in *Warner-Lambert*) may not be asserted under § 271(e)(2)(A), but may of course be asserted in a traditional infringement action under 35 U.S.C. § 271(b) after ANDA approval and commercial marketing.

Under *Warner-Lambert* and the decision below, NDA-holders may no longer use off-label use patents under § 271(e)(2)(A) as a sword to prevent competition from generic applicants seeking approval to market off-patent drugs for FDA-approved uses. That is precisely what Allergan, and Warner-Lambert before it, accomplished. Merely by asserting patents on unapproved uses for

which they consciously chose not to seek FDA approval, and for which generic applicants could not by law promote, Allergan and Warner-Lambert preserved their lucrative monopolies on off-patent drugs and off-patent FDA-approved uses for years. And both Warner-Lambert and Allergan sought the powerful relief under Hatch-Waxman in § 271(e)(4) that would prevent ANDA applicants from ever marketing their drugs for any use for the life of the off-label use patents, even those FDA-approved off-patent uses in the public domain. Congress, of course, never intended to confer the invaluable 30-month stay and broad § 271(e)(4) relief provided by Hatch-Waxman on NDA-holders like those here that decided not to make the investment required to obtain a new FDA-approved use that might benefit patients.

Allergan's petition tries to revive this cheap but effective means of staving off generic competition by asking this Court to overrule the statutory holding of *Warner-Lambert*. This Court should deny the petition. There is no split of authority or conflict either outside or within the Federal Circuit. The judges of the Federal Circuit have, by their votes, unanimously agreed that *Warner-Lambert* correctly interpreted § 271(e)(2)(A). Rightly so—that interpretation is consistent with the provision's plain language and comports with Hatch-Waxman's patent-listing and certification provisions, as well as Congress's underlying goal of making available to the public more lower-cost generic drugs.

The *per curiam* decision below, like *Warner-Lambert* before it, does not affect, much less restrict, the incentive to invest in research on new uses where, as here, the NDA-holder never made any investment to obtain FDA approval for the new use. Such off-label use patents can still be asserted against generic applicants, albeit without the automatic 30-month stay and the broad § 271(e)(4) relief that is reserved for actions on patents that claim approved uses of the drug.

ARGUMENT

I. There is no conflict warranting review.

Because the Federal Circuit has exclusive jurisdiction over all patent appeals, 28 U.S.C. § 1295, there is—and can be—no conflict or split of authority among the various circuit courts of appeals on the proper interpretation of § 271(e)(2)(A). Nor is there any conflict within the Federal Circuit itself, as there was in prior patent decisions of the Federal Circuit reviewed by this Court. *See, e.g., Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 122 S. Ct. 1831 (2002); *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 117 S. Ct. 1040 (1997).

The Federal Circuit distributes draft precedential opinions to all active judges for comment before issuance. *See* FED. CIR. INTERNAL OPERATING PROC., RULE 10. Accordingly, the judges of the Federal Circuit, including the judges on the *Allergan* panel below, had the opportunity to comment on the *Warner-Lambert* decision before it issued. *Warner-Lambert* nonetheless issued as a unanimous panel decision.

The *Allergan* draft opinion likewise circulated to all active Federal Circuit judges for comment before it issued. The court could have *sua sponte* ordered *en banc* review, as it has done in the past. *See e.g., Paulik v. Rizkalla*, 760 F.2d 1270 (Fed. Cir. 1985) (convening *en banc* to resolve issues under 35 U.S.C. § 102(g)); *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988) (convening *en banc* on limited issue of inequitable-conduct standards); *Johnson & Johnston v. RE Serv.*, Fed. Cir. Docket Nos. 99-1076, -1179, -1180 (Order of Jan. 24, 2001) (*sua sponte* convening *en banc* after panel circulated opinion but before opinion issued); *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, Fed. Cir. Docket Nos. 01-1357, -1376, 02-1221, -1256 (Order of Sept. 26, 2003) (*sua*

sponte convening *en banc* regarding issues of willful infringement and the possible need to overrule conflicting cases). But the court evidently did not feel that *en banc* review was desirable. Instead, *Allergan* issued as a unanimous *per curiam* panel opinion applying and affirming the holding in *Warner-Lambert*. *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322 (Fed. Cir. 2003), *rehearing en banc denied* (May 22, 2003).

The Federal Circuit's decision to deny Allergan's petition for rehearing *en banc* was likewise unanimous. *See Allergan, Inc. v. Alcon Labs., Inc.*, Fed. Cir. Docket No. 02-1449 (Order of May 22, 2003). Thus, not even a single judge on the *Allergan* panel went on record to oppose denial of rehearing *en banc*.

Despite the abstract intellectual disagreement between the *Warner-Lambert* panel and the *Allergan* concurrers, the Federal Circuit found the case undeserving of *en banc* review. The law in the Federal Circuit—and across the country—is thus uniform: no cause of action exists under § 271(e)(2)(A) for infringement of method-of-use patents that claim off-label uses. This Court's intervention is not warranted.

II. The Federal Circuit's *per curiam* opinion is consistent with both the plain language and the purpose of the Hatch-Waxman Act.

At issue here is the proper construction and interpretation of § 271(e)(2)(A), which provides in pertinent part:

> It shall be an act of infringement to submit [an ANDA] for a drug . . . the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under [the Hatch-Waxman Act] to engage in the commercial manufacture, use, or sale of

> a drug . . . the use of which is claimed in a patent before expiration of such patent.

35 U.S.C. § 271(e)(2)(A). In *Warner-Lambert*, the Federal Circuit addressed whether Congress intended to limit actions for infringement of method-of-use patents under § 271(e)(2)(A) to patents that claim an FDA-approved use of a drug. *See Warner-Lambert*, 316 F.3d at 1354. In a thorough, well-reasoned decision, the panel answered that question yes, holding "it is not an act of infringement to submit an ANDA for approval to market a drug for a use when neither the drug nor that use is covered by an existing patent and the patent at issue is for a use not approved under the NDA." *Id.* at 1354-55.

This analysis was and is correct, as the entire Federal Circuit later implicitly acknowledged when it denied *en banc* rehearing in the case at bar. The plain language of § 271(e)(2)(A)—the initial focus in a statutory construction analysis, *see Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 438, 119 S. Ct. 755, 760 (1999)—indicates that it applies only to an ANDA that seeks approval for the patented use. But because an ANDA may never seek approval for an *off-label* use of a drug, *see* 21 U.S.C. § 355(j)(2)(A)(i), it follows that this provision does not apply to an off-label use patent. In other words, the term "the use" in § 271(e)(2)(A) refers to "the" FDA-approved use, "the" only use for which an ANDA applicant can ever seek approval. That Congress chose to use the definite and particularized article "the" in referring to "the drug" is also significant because "the" is a word of limitation that refers to a specific use, which in this case must be the FDA-approved use listed in the NDA. *See Am. Bus. Ass'n v. Slater*, 231 F.3d 1, 4-5 (D.C. Cir. 2000).

This construction of § 271(e)(2)(A) is reinforced by reading the Hatch-Waxman Act as a whole, and in conjunction with its underlying purpose, as it must be read. *See Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 669, 110 S. Ct. 2683, 2688 (1990) (affirming interpre-

tation of § 271(e)(1) that best fit with the structure of the Hatch-Waxman Act taken as a whole); *U.S. Nat'l Bank of Or. v. Indep. Ins. Agents of Am., Inc.*, 508 U.S. 439, 455, 113 S. Ct. 2173, 2182 (1993) ("[I]n expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy.") (internal quotations and citation omitted); *Kokoszka v. Belford*, 417 U.S. 642, 650, 94 S. Ct. 2431, 2436 (1974) (court must give statute "such a construction as will carry into execution the will of the Legislature.") (internal quotations and citation omitted). The *Warner-Lambert* construction is consistent with the legislative purpose of Hatch-Waxman, which is "to get generic drugs into the hands of patients at reasonable prices—fast." *In re Barr Labs.*, 930 F.2d 72, 76 (D.C. Cir. 1991).

On the other hand, the construction advanced by Allergan would thwart that salutary purpose by permitting an NDA-holder to forestall generic competition indefinitely—even where the applicant seeks approval to market an off-patent drug for an off-patent use. Congress did not intend such a result, and Allergan does not explain how its construction—which is very good for NDA-holders but would squelch generic competition altogether—can be squared with the underlying purpose of Hatch-Waxman.

The *Warner-Lambert* panel's construction of § 271(e)(2)(A) is also the only interpretation consistent with Hatch-Waxman's patent-listing and patent-certification provisions. Only information on method-of-use patents that claim a method of using the drug for which the NDA was submitted may be submitted to the FDA for listing in the Orange Book. *See* 21 U.S.C. §§ 355(b)(1), (c)(2). The FDA has interpreted this provision to mean that only patents that claim an approved use of the NDA drug should be submitted for listing in the Orange Book. *See* 21 C.F.R. § 314.53(b)(1). Likewise, an ANDA applicant need certify only to a use patent that

"claims a use for such listed drug for which the applicant is seeking approval," 21 U.S.C. § 355(j)(2)(A)(vii), which necessarily excludes off-label method-of-use patents since an ANDA applicant may never seek approval for an unapproved use of a drug. The legislative history is in accord. *See* H.R. Rep. No. 98-857, pt. 1, at 22 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2655 (applicant must submit certification only for use patents that claim an indication for which the applicant is seeking approval).

This is also the only interpretation of § 271(e)(2)(A) that does not lead to absurd results and run afoul of the patent laws. *See Clinton v. City of New York*, 524 U.S. 417, 429, 118 S. Ct. 2091, 2098 (1998) (statutes should be interpreted to avoid absurd results). NDA-holders have argued that, under § 271(e)(4), a finding of infringement entitles the patentee to an order barring approval of the ANDA altogether for the life of the asserted patent. *See* 35 U.S.C. § 271(e)(4). By allowing an off-label use patent to be asserted under § 271(e)(2)(A), as Allergan seeks to do here, a patentee could prevent marketing of the drug for any use, even admittedly non-infringing or off-patent uses—an absurd result that is, in the words of the *Allergan* district court, "akin to using a sledgehammer to squash an ant." *Allergan, Inc. v. Alcon Labs., Inc.*, 200 F. Supp. 2d 1219, 1232 (C.D. Cal. 2002). Such an interpretation also runs afoul of the patent laws, under which off-patent subject matter passes to the free use of the public. A patentee has the right to exclude others from practicing only that which infringes. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152, 109 S. Ct. 971, 978 (1989).

Thus, all the relevant tools of statutory construction point to the same conclusion and mandate that § 271(e)(2)(A) be interpreted consistent with the *per curiam* opinion below and *Warner-Lambert*—to exclude off-label method-of-use patents.

III. The statutory interpretation established in *Warner-Lambert*, and upheld in *Allergan*, is in the public's best interest, is consistent with this Court's precedent, and provides no disincentives to research new uses for existing drugs.

Contrary to Allergan's contentions, the Federal Circuit has not created a disincentive for researching new uses of old drugs. The incentive for NDA-holders created by Hatch-Waxman was patent-term restoration, which applies only where the NDA-holder makes the investment to obtain FDA approval for a patented drug product or use in order to benefit the consuming public. *See Eli Lilly*, 496 U.S. at 670-71, 110 S. Ct. at 2689. Nothing suggests that Congress intended to confer any benefit on an NDA-holder, like Allergan here, that strategically decided *not* to make that investment. *Warner-Lambert*, 316 F.3d at 1359 ("There is no evidence that Congress intended to enable an innovator to extend its exclusivity merely by asserting patents on unapproved uses.").

Although Allergan extols the fact that it has invested money into researching brimonidine's neuroprotective uses, Allergan admits it did not perform the studies required for FDA approval of these uses. Allergan tried to obtain patent protection on the use of brimonidine to reduce intraocular pressure and as a neuroprotectant, but the Patent Office rejected a patent for the former use and Allergan settled for patent protection only on neuroprotection. Allergan did not appeal these rejections to the Board of Patent Appeals or the courts. As such, Allergan settled for patent protection on a use for which it chose *not* to pursue FDA approval. Nothing legally precluded Allergan from pursuing FDA approval on the patented neuroprotection. Had it done so, it could have had patent protection on a use for which it has FDA approval, and it could have used that protection against later generic ANDA-filers. But Allergan did not do so. Thus, Allergan

is where it is due to its own decisions, and not any error by the Federal Circuit.

Nevertheless, Allergan still has the ability to sue a generic-drug manufacturer for inducement of infringement once the generic company brings its product to market. Under the construction applied in the *per curiam* opinion below, Allergan simply does not get the rewards that Hatch-Waxman bestows on those who undertake the effort to seek FDA approval on a patented use. Otherwise, Allergan's patent rights are unaffected, and are the same now as they were before *Warner-Lambert*, *i.e.*, they can be used to prevent the active and knowing promotion and inducement of the protected off-label use once the generic proceeds to market. The only difference is that Allergan does not get the free 30-month injunction without actually proving a likelihood of success on the merits of its infringement claim, together with the other elements necessary for such injunctive relief.

While Allergan complains that a post-marketing preliminary injunction against a generic manufacturer is "illusory," Allergan's real complaint is that such an injunction might be hard to get or would not be broad enough to inhibit all market access to a product that has substantial non-infringing or unpatented uses. But under the patent laws, one is not entitled to enjoin non-infringing or unpatented uses, a fundamental proposition not at issue here. *See Bonito Boats*, 489 U.S. at 152, 109 S. Ct. at 978 ("We have long held that after the expiration of a federal patent, the subject matter of the patent passes to the free use of the public as a matter of federal law."). Allergan thus simply wants more than it is entitled to under the patent laws.

The statutory construction proposed by Allergan actually creates a perverse incentive, encouraging NDA-holders to refrain from seeking FDA approval for patented uses:

> [H]olders of method-of-use patents can benefit by *not* seeking FDA approval for the patented use. By so doing, they force the generic manufacturers to file paragraph IV certifications, which then triggers the thirty-month extension that Hatch-Waxman adds to their period of exclusivity.

Organon Inc. v. Teva Pharms., Inc., 244 F. Supp. 2d 370, 374 n.5 (D.N.J. 2002).

In sum, Allergan did nothing more than list patents that block generic competition with no corresponding value to patients. There is no need for an incentive to encourage *that* type of conduct.

Finally, Allergan's contention that the Federal Circuit's interpretation of § 271(e)(2) threatens future disruptions in healthcare is unfounded. Allergan's argument teeters on the uncertain premise of an injunction against a generic manufacturer, followed by the unlikely possibility that a doctor will be unable to find another prescription drug product to take the place of the generic drug and prevent withdrawal symptoms. Allergan cannot demonstrate how often, if ever, this unlikely chain of events might occur, nor can it show why the mere threat of possible disruptions means that patients would be better off *not* having faster access to lower-cost drug products.

Companies like Allergan have the same financial incentives to develop new drugs now as they did before *Warner-Lambert*, and the public interest is served by the elimination of the 30-month stay that can accompany a suit brought by an NDA-holder on an off-label use patent.

CONCLUSION

For these reasons, the petition should be *denied*.

Respectfully submitted,

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